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Guidance for the Reregistration of Pesticide Products Containing Fenamiphos as the Active Ingredient

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GUIDANCE FOR THE REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

FENAMIPHOS

AS THE ACTIVE INGREDIENT

CASE NUMBER: GS 0333

CAS NUMBER: 22224-92-6

JUNE, 1987

ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF PESTICIDE PROGRAMS

WASHINGTON, D.C. 20460

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This document contains information regarding the registration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of date requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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I. INTRODUCTION

EPA has established the Registration Standards program in order to provide an orderly mechanism by which pesticide products containing the same active ingredient can be reviewed and standards set for compliance with FIFRA. The standards are applicable to reregistration and future applications for registration of products containing the same active ingredient. Each registrant of a product containing an active ingredient subject to this Standard who wishes to continue to sell or distribute that product must bring his product and labeling into compliance with FIFRA, as instructed by this Standard.

The Registration Standards program involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criteria of FIFRA. In its review EPA identifies:

1. Studies that are acceptable to support the data requirements for the currently registered uses of the pesticide.

2. Additional studies necessary to support continued registration. The additional studies may not have been required when the product was initially registered or may be needed to replace studies that are now considered inadequate.

3. Labeling revisions needed to ensure that the product is not misbranded and that the labeling is adequate to protect man and the environment.

The detailed scientific review, which is not contained in this document, but is available upon request[1], focuses on the pesticide active ingredient. The scientific review primarily discusses the Agency's evaluation of and conclusions from available data in its files pertaining to the pesticide active ingredient. However, during the review of these data the Agency is also looking for potential hazards that may be associated with the end use products that contain the active ingredient. The Agency will apply the provisions of this Registration Standard to end use products if necessary to protect man and the environment.

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[1] The scientific reviews may be obtained from the Information Services Section, Program Management and Support Division (TS-757C), EPA, 401 M St., SW, Washington, D.C. 20460.

EPA's reassessment results in the development of a regulatory position, contained in this Registration Standard, on the pesticide and each of its registered uses. See Section IV - Regulatory Position and Rationale. Based on its regulatory position, the Agency may prescribe a variety of steps to be taken by registrants to maintain their registrations in compliance with FIFRA. These steps may include:

1. Submission of data in support of product registration;

2. Modification of product labels;

3. Modifications to the manufacturing process of the pesticide to reduce the levels of impurities or contaminants;

4. Restriction of the use of the pesticide to certified applicators or other specially trained individuals;

5. Modification of uses or formulation types; or

6. Specification of packaging limitations.

Failure to comply with these requirements may result in the issuance of a Notice of Intent to Cancel or a Notice of Intent to Suspend (in the case of failure to submit data).

In addition, in cases in which hazards to man or the environment are identified, the Agency may initiate a special review of the pesticide in accordance with 40 CFR Part 154 to examine in depth the risks and benefits of use of the pesticide. If the Agency determines that the risks of the pesticide's use outweigh the benefits of use, the Agency may propose additional regulatory actions, such as cancellation of uses of the pesticide which have been determined to cause unreasonable adverse effects on the environment.

EPA has authority under the Data Call-In (DCI) provisions of FIFRA sec. 3(c)(2)(B) to require that registrants submit data to answer our questions regarding the chemical, toxicological, and environmental characteristics and fate of a pesticide. This Registration Standard lists the data EPA believes are necessary to resolve our concerns about this pesticide. These data are listed in the Tables A, B, and C in Appendix I. Failure to comply with the DCI requirements enumerated in this Registration Standard may result in issuance by EPA of a Notice of Intent to Suspend the affected product registrations.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants should notify the Agency of any information, including interim or preliminary results of studies, if those results suggest possible unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

II. CHEMICAL COVERED BY THIS STANDARD

A. Description of chemical

The following chemical is covered by this Registration Standard:

Common name: Fenamiphos

Chemical name: O-ethyl-O-(3-methyl-4-methyl-thiophenyl)-isopropylphosphoramidate

CAS number: 22224-92-6

OPP (Shaughnessy) number: 100601

Empirical formula: $C_{13}H_{22}NO_3PS$

Trade names: Nemacur® 15G, Nemacur® 3

Basic registrant: Mobay Chemical Company

B. Use Profile

Type of Pesticide: Systemic Nematicide/Insecticide

/ Pests Controlled: Nematodes, Thrips

Registered Uses: terrestrial food crops, terrestrial non-food sites

Predominant Uses: field and vegetable crops, orchards, vineyards, non-bearing orchards, nursery stock, ornamentals

Mode of Activity: Organophosphate/Cholinesterase Inhibitor

Formulation Types Registered:

85% Nemacur® Technical
72.3% Nemacur® Concentrate
Nemacur® 3 EC (3 lb/gal emulsifiable concentrate)
Nemacur® 2 EC (2 lb/gal emulsifiable concentrate)
Nemacur® 15 G (granular)
Nemacur® 10 G (granular)
Nemacur® 5 G (granular)

Methods of Application: Soil treatment by ground spray equipment, by granular application equipment or by incorporation into irrigation water. Soil incorporation or irrigation immediately after treatment is required. The EC formulation is currently a restricted use pesticide and applicators must be certified or under direct supervision of a certified applicator.

III. AGENCY ASSESSMENT

A. SUMMARY

Based on the review of the available data, the Agency has reached the conclusions set forth in this Standard. A summary of those conclusions follows. A more detailed discussion is contained in the remainder of this chapter.

1. The major hazard concern is the potential for acute toxicity to humans and to fish and wildlife from exposure to formulated fenamiphos products. Technical fenamiphos is acutely toxic to laboratory animals, Toxicity Category I, by the oral, dermal, and inhalation routes of exposure. It is also very highly toxic to birds as well as to cold and warm water fish. Fenamiphos has also been shown to cause reproductive impairment in waterfowl and upland game birds. Field kills (birds and mammals) have occured in many instances in areas after fenamiphos application. All uses of fenamiphos exceed restricted use criteria for fish and wildlife; 1/5 the acute oral LD_{50} for mammals, 1/5 the subacute dietary LC_{50} for birds, and 1/10 the acute LC_{50} for aquatic organisms. The Agency has concluded that the risks to fish and wildlife associated with unrestricted use of fenamiphos constitute unreasonable adverse effects; therefore, all products are being restricted.

2. Studies using both the granular and spray formulations of fenamiphos according to label directions have shown some avian and mammalian mortality. These studies suggest that soil incorporation and/or irrigation immediately following application will reduce hazards to non-target avian and mammalian species. A terrestrial field study is necessary to determine if the hazards indicated by laboratory and simulated field studies are below levels of concern for mammalian and avian species under actual use conditions.

3. Both aerial application of fenamiphos as well as runoff exposure pose a potential hazard to fish species indigenous to small lakes, ponds, and streams. Aquatic contamination from aerial application could occur when fenamiphos is applied as a broadcast spray to crops irrigated by interconnected waterways and could result in residues that exceed LC_{50} values. Estimated environmental concentrations for runoff also exceed LC_{50} values. Simulated and actual field testing of aquatic organisms is required to assess potential exposure and toxicity to aquatic organisms.

4. Fenamiphos is not oncogenic in rats or mice. The dietary cholinesterase no-observable-effect level (NOEL) for fenamiphos is 1.0 ppm for both rodents and non-rodents. No adverse reproductive effects were observed in a 3-generation rat reproductive study. Evidence regarding developmental effects resulting from fenamiphos are inconclusive. Teratology studies in the rat and rabbit are required. Fenamiphos was negative for mutagenic effects in the test systems assayed.

5. Many of the tolerances are supported by residue data. However, data are required for garlic, soybeans, grapes, bananas, cocoa beans, cottonseed, peanuts, pineapple, tobacco, and nonbearing orchard crops. The adequacy of tolerances for residues in animal commodities will be assessed after required animal metabolism data and residue data for feed items are submitted and reviewed. A provisional acceptable daily (PADI) intake has been set at 0.00025 mg/kg/day. This is based on the no-observable effect level (NOEL) from a 2-year dog feeding study of 0.025 mg/kg/day (1 ppm) for cholinesterase inhibition, and an uncertainty factor of 100 which accounts for the lack of an acceptable teratology study. The Theoretical Maximum Residue Contribution (TMRC) for the U.S. population average based on anticipated residues and percent crop treated, is 0.00011 mg/kg/day which corresponds to 42% of the PADI. It is possible that resolution of the teratology data gap will allow for a lower uncertainty factor which will result in a higher ADI and consequently a lower percentage of the ADI occupied by the TMRC.

6. Except for hydrolysis and photodegradation studies in water, the available data are insufficient to fully assess the environmental fate of fenamiphos. Additional enviromental fate data are required. The potential for fenamiphos to reach ground water cannot be assessed until the acceptable environmental fate studies are received and reviewed by the Agency.

As a result of this review, the Agency has identified data necessary to further evaluate the environmental and human risks associated with the use of fenamiphos. These data must be submitted in order to maintain registrations of products or register new products containing fenamiphos. A summary of these data gaps appears in Table 1. Note that this is only a summary and complete details can be obtained by referring to the tables in Appendix I.

The Agency has determined that certain label restrictions or revisions are necessary in order for fenamiphos products to remain in compliance with FIFRA. These include:

- Restricted Use Classification
- Environmental Hazards Precautions
- Endangered Species
- Reentry Interval
- Protective Clothing

Chapter IV, Section D, contains the specific wording for each of the labeling statements and identifies the products to which each labeling statement applies.

Chapter IV, Section A, Regulatory Position and Rationale, discusses the Agency's position regarding fenamiphos.

TABLE 1

SUMMARY OF DATA GAPS FOR FENAMIPHOS

(Refer to Appendix I, Data Tables, for detailed information and due dates.)

Product Chemistry: All

Residue Chemistry:

- Animal Metabolism
- Residue Analytical Methods (plants and animals)
- Storage Stability Data
- Residue Studies

Environmental Fate:

- Photodegradation (soil)
- Aerobic and Anaerobic Soil Metabolism
- Leaching and Adsorption/Desorption
- Volatility (lab)
- Soil Dissipation
- Rotational Crops (confined and field)
- Fish Accumulation
- Spray Drift Droplet Spectrum and Field Evaluation
- Reentry

Toxicology:

- 21-Day Inhalation (rat)
- Teratology (rat and rabbit)
- Mutagenicity
- Metabolism

Ecological Effects:

- Simulated and Actual Field Testing (birds and mammals)
- Freshwater Fish Toxicity
- Freshwater Invertebrate Acute Toxicity
- Acute Toxicity to Estuarine and Marine Organisms
- Fish Early Life Stage
- Aquatic Invertebrate Life Cycle
- Fish Life Cycle
- Aquatic Organism Accumulation
- Simulated and Actual Field Testing Aquatic Organisms

B. PRELIMINARY RISK ASSESSMENT

Toxicological Studies - Fenamiphos. Several data gaps exist for fenamiphos so definitive conclusions cannot be reached for certain toxicological effects until additional data is received and reviewed. The following assessment is based on the data available.

1. Acute Toxicity and Irritation Studies. Adequate acute studies exist to define the acute toxicity of fenamiphos products. Technical fenamiphos is acutely toxic, (Toxicity Category I), by the oral route (LD_{50} 2.7 mg/kg), dermal route (LD_{50} 178.8 mg/kg), and inhalation route (LC_{50} 0.1 mg/L) of exposure.

   Technical fenamiphos is slightly irritating to the eye (Toxicity Category III) but is not a dermal irritant (Toxicity Category IV). Technical fenamiphos is not a dermal sensitizer or a delayed neurotoxicant.

   No further acute toxicity studies are required at this time.

2. Subchronic Testing

   Oral (Rodent, Non-Rodent) Studies:

   In a 90-day feeding study, fenamiphos was fed to Wistar rats at levels of 0, 4, 8, 16, and 32 ppm for 90 days. There was no mortality at the levels fed but cholinergic signs of toxicity were observed in animals at the 32 ppm level. A dose-related decrease in plasma cholinesterase values by 34 to 44 percent was reported in female rats for dietary levels of 8, 16, and 32 ppm. Maximum cholinesterase inhibition was observed within the first week of the study for males and by the eighth week for female rats. Erythrocyte cholinesterase inhibition was observed for animals fed dietary levels of 16 and 32 ppm. The no-observable-effect level (NOEL) for cholinesterase inhibition is 4 ppm. No significant difference in male or female relative organ weights between the control and test groups was reported. No histopathological findings were reported as being attributed to the test material.

In a second subchronic study, Beagle dogs were fed dietary levels of 0, 1, 2, and 5 ppm fenamiphos for 90 days. A decrease in body weight gain was reported for females at the highest dose level (5 ppm). Plasma cholinesterase was inhibited by more than 20 percent for dietary levels of 2 and 5 ppm with a greater than 20 percent decrease in erythrocyte cholinesterase activity reported for the 5 ppm level. Cholinesterase inhibition was dose related and occurred during the fourth week of the study. The NOEL for cholinesterase inhibition is 1.0 ppm.

No further subchronic oral studies are required at this time.

Dermal Studies. An aqueous formulation of 89.8% technical fenamiphos was applied to New Zealand rabbits at 0, 0.5, 2.5 and 10 mg/kg body weight for a 6 hour exposure 5 days a week for 3 weeks. Half of the animals were abraded. A decrease in body weight gain was observed for both sexes at the highest dose tested, 10 mg/kg day. A decrease in alanine aminotransferase was reported at the 2.5 and 10.0 mg/kg/day levels of 33 and 20 percent, respectively, in female rabbits. Plasma and brain cholinesterase were depressed at 2.5 and 10 mg/kg/day in female rabbits. Plasma and erythrocyte cholinesterase in male rabbits and erythrocyte cholinesterase in female rabbits were decreased at 10 mg/kg/day. The NOEL for plasma, erythrocyte or brain cholinesterase inhibition is 0.5 mg/kg/day.

No further subchronic dermal studies are required at this time.

There are no 90-day subchronic dermal toxicity studies on fenamiphos. The registered uses of fenamiphos do not require this study.

Inhalation Studies. A 21-day inhalation study is required because fenamiphos is registered for use on tobacco.

Neurotoxicity Studies. There are no subchronic neurotoxicity studies on fenamiphos. Fenamiphos was negative for neurotoxicity in the acute delayed neurotoxicity study and is without evidence of delayed neurotoxicity in other mammalian species. Therefore, a subchronic neurotoxicity study is not required.

3. Chronic Testing

Chronic Toxicity Studies. There are sufficient data available to define the long term effects of fenamiphos.

Fenamiphos was fed to Fischer 344 rats (50/sex/group) for 2 years at dietary levels of 0, 2, 10, and 50 ppm. A decrease in body weight gain was reported for the 50 ppm level accompanied by a transient decrease in food consumption for female rats of the high dietary level (50 ppm). Of the organs weighed, at the termination of the study a decrease in absolute liver weight and an increase in absolute and relative lung weights were reported for the 50 ppm level. A dose related decrease in plasma and erythrocyte cholinesterase activity was observed for males and females of all three dietary levels by the sixth week of the study. Over the duration of the study the plasma cholinesterase values at 2 ppm were depressed by 6 to 38 percent in males and 22 to 42 percent in females, while erythrocyte cholinesterase was depressed by 2 to 7 percent in males and 3 to 11 percent in females. Brain cholinesterase activity for males at the low-dose level (2 ppm) was depressed by 5 percent with the female values comparable to the control cholinesterase values. The cholinesterase NOEL for this study is less than 2 ppm. However, in a concurrent subchronic rat feeding study dietary levels of 0.36, 0.6 and 1.0 ppm were fed to male and female rats for 90 days without effect on plasma, erythrocyte, or brain cholinesterase values. The rat cholinesterase NOEL for fenamiphos is 1.0 ppm. The systemic NOEL from the two year rat study is 10 ppm.

No dose-related increase in neoplastic and non-neoplastic histopathological lesions was observed from feeding dietary levels of 2, 10, and 50 ppm to male and female rats for 2 years.

Fenamiphos was fed to 8 month old Beagle dogs (four/sex/group) at dietary levels of 0, 0.5, 1.0, 2.0, 5.0, and 10 ppm for 2 years. No effects were observed for the following parameters at levels up to and including 10 ppm: appearance, growth rate, food consumption, mortality, hematology, and clinical chemistry. No gross (including organ weights) or histopathological changes were attributed to dietary levels of fenamiphos. Plasma cholinesterase activity was depressed at the 2, 5, and 10 ppm dietary levels with erythrocyte cholinesterase activity depressed at the 5 and 10 ppm levels in both sexes. Brain cholinesterase values were not determined.

In a subsequent subchronic feeding study dietary levels of 0, 0.6, 1.0, and 1.7 ppm were fed to 4 month old Beagle dogs (4/sex/group) for 100 days. Plasma cholinesterase activity was depressed by 28 to 35 percent only in males fed the 1.7 ppm level. Erythrocyte and brain cholinesterase activity were not affected at any of the dietary levels tested.

The cholinesterase NOEL based on a 2-year dog feeding study is 1.0 ppm with the lowest effect level for cholinesterase inhibition determined to be 2 ppm. The systemic NOEL based on a 2-year dog feeding study is 10 ppm, the highest level fed.

No further chronic toxicity studies are required at this time.

Oncogenicity. There are sufficient data available to determine that fenamiphos is not oncogenic in rats or mice.

Fischer 344 rats (50/sex/group) were fed dietary levels of 0, 2, 10, and 50 ppm for 2 years. No dose-related increase in neoplastic or nonneoplastic histopathological lesions was observed as compared to the control animals.

In another study, CD outbred strain albino mice (50/sex/group) were fed dietary levels of 0, 2, 10 and 50 ppm for eighteen months. Statistically significant increases in mean relative brain weight and decreased body weight were reported in females fed 50 ppm. Fenamiphos was not shown to be oncogenic.

No further oncogenicity studies are required at this time.

Teratology. Sufficient data are not available to determine the teratogenicity of fenamiphos in rabbits.

New Zealand rabbits (20 females/group) were administered

88.8% fenamiphos orally in corn oil at doses of 0, 0.1, 0.3, and 1.0 mg/kg body weight from days 6 to 18 of gestation. Maternal toxicity was observed at the 0.3 and 1.0 mg/kg dosage levels consisting of a decrease in mean body weight gain accompanied by a 90 and 88 percent survival, respectively. Liver lesions were observed at the 1.0 mg/kg level. Mean fetal weight was slightly depressed at 1.0 mg/kg. One dam at 0.3 mg/kg aborted one dead pup on day 25. Two dams at 1.0 mg/kg aborted on days 26 and 28 with eight dead pups and seven late resorptions, respectively. In addition, one dead fetus was observed in each of two litters at the high-dose during Cesarean section. A significant increase in the incidence of chain-fused sternebrae was noted at 1.0 mg/kg, with a finding of five fetuses in three litters. There was also one fetus in one litter at 0.3 mg/kg with a finding of chain-fused sternebrae. Fenamiphos caused an increased incidence in a minor anomaly (left carotid artery arising from the innominate) at all three dose levels, which was greater than the spontaneous occurrence in the historical controls. Although apparently compound-related, the response did not increase in a dose-response relationship. Owing to the physical status of all dams in the study (evidence of ascites and pitted kidneys) a clear relationship between compound administration and effect cannot be established and the study is considered supplementary. Therefore, the biological significance of the responses observed must be clarified.

A rabbit teratology study is required.

There are not sufficient data available to assess the teratogenicity of fenamiphos in rats. A rat teratology study is required.

Reproduction. An adequate study in rats assessing the reproductive effects of fenamiphos over at least two generations is available. Thirty-three-day old FB30 rats (10 males/20 females/group) were fed dietary levels of 0, 3, 10 and 30 ppm through three generations. Dietary levels of 3 and 10 ppm had no effect on behavior or body weight gain of the males or females. Male rats of the F2b generation fed 30 ppm gained less weight than the control males of the same generation. There was no difference between the test and control animals with respect to fertility, litter size, average weight of pups at birth, and lactation performance of the dams. The reproduction NOEL is 30 ppm.

No further reproduction studies are required at this time.

Mutagenicity Studies. Fenamiphos was negative when tested in the CHO/HGPRT mutation assay and in the dominant lethal mutation assay. Data are required however, to assess direct DNA damage.

4. Metabolism Studies. Data are not available to determine the degree of tissue accumulation and elimination in rats resulting from multiple doses of fenamiphos. The major metabolites of fenamiphos have been identified from single dose studies as the sulfoxide and sulfone. However, the metabolic pathway for the desisopropyl metabolites needs to be defined.

A guideline multiple dose rat metabolism study is required.

The sulfoxide, sulfone, and des-isopropyl analogs of fenamiphos are as highly toxic as the technical material; the phenolic metabolites are low in acute toxicity.

5. Special Studies.

Antidotal. Sufficient data are available to determine the efficacy of atropine and 2-PAM in treating fenamiphos poisoning in male and female rats.

Atropine increased the LD_{50} of fenamiphos by five times and 2-PAM increased the LD_{50} of fenamiphos by six times the value for untreated animals. The combination of atropine and 2-PAM were no more protective than either compound alone.

6. Risk Assessment

- Fenamiphos is acutely toxic to laboratory animals, Toxicity Category I, by the oral, dermal, and inhalation routes of exposure.
- Fenamiphos is not a delayed neurotoxicant.
- Fenamiphos is not oncogenic in rats or mice.
- No dose-related increase in neoplastic and non-neoplastic histopathological lesions was observed from feeding dietary levels of 2, 10, and 50 ppm to male and female rats for 2 years. No gross or histopathological changes were attributed to feeding dietary levels of .5 to 10 ppm to Beagle dogs for 2 years. The dietary cholinesterase NOEL for fenamiphos is 1.0 ppm for both rats and dogs.
- There is not sufficient data to fully assess the teratogenic potential for fenamiphos. Further studies in the rat and rabbit are required.
- No adverse reproductive effects were observed in a 3-generation rat reproductive study.
- Fenamiphos was not mutagenic in the test systems assayed.

C. OTHER SCIENCE FINDINGS

Environmental Fate. Available data are insufficient to fully assess the environmental fate of fenamiphos. Except for data pertaining to hydrolysis and photodegradation in water, the information discussed below is considered supplementary and is provided from studies that did not fulfill the data requirements for registration; the later studies must be repeated.

1. Hydrolysis. A radiolabeled hydrolysis study demonstrates that fenamiphos degrades with half-lives of 7 to 14 days at pH 3, >30 days at pH 9, and appears to be stable at pH 7 when incubated in the dark at 30°C. This data suggests that fenamiphos is relatively stable in neutral and alkaline solutions. The primary degradation product in the pH 3 solution was deaminated fenamiphos (74-78%). Degradates identified in the methylene chloride extracts from pH 3, 7, and 9 solutions included fenamiphos sulfoxide, fenamiphos sulfone, fenamiphos phenol, fenamiphos sulfoxide phenol, and fenamiphos sulfone phenol. No further hydrolysis studies are required.

2. Photodegradation in Water. A radiolabeled degradation study demonstrates that fenamiphos degrades with a half-life of 2 to 4 hours in pH 7 buffered water irradiated with artificial light. After 24 hours of irradiation, fenamiphos accounted for approximately 4% of the applied radioactivity, fenamiphos sulfonic acid phenol for approximately 19%, fenamiphos sulfoxide for approximately 17%, fenamiphos sulfonic acid for 6%, and fenamiphos sulfoxide phenol for 1%. No further water photodegradation studies are required.

3. Photodegradation in Soil. Ring-labeled fenamiphos degraded with a half-life of <1 hour on sandy loam soil irradiated with artificial light. After 48 hours of irradiation, fenamiphos and the degradates fenamiphos sulfoxide and fenamiphos sulfone accounted for approximately 12, 55, and 6% of the extractable radioactivity, respectively. This study does not fulfill data requirements because the material balance was incomplete; not all the material was accounted for. Data on the photodegradation of fenamiphos in soil are required.

4. Aerobic Soil Metabolism. Available data are inadequate to assess the metabolism of fenamiphos in aerobic soil. The study does not fulfill data requirements because the soil was not characterized and the material balance was incomplete. Data on the metabolism of fenamiphos in aerobic soil are required.

5. Anaerobic Soil Metabolism. Data on the metabolism of fenamiphos in anaerobic soil are required.

6. Leaching and Adsorption/Desorption Studies. Available data (8 studies) are inadequate to assess leaching and adsorption/desorption. Data on leaching and adsorption/desorption of fenamiphos are required.

7. Laboratory Volatility Studies. No data were reviewed. Laboratory volatility studies are required.

8. Field Volatility Studies. The data requirement is deferred pending receipt of acceptable laboratory volatility studies.

9. Terrestrial Field Dissipation Studies. Available data (11 studies) are inadequate to assess terrestrial field dissipation. Data on the terrestrial field dissipation of fenamiphos are required.

10. Aquatic Field Dissipation. No data were reviewed; however, no data are required because fenamiphos has no registered aquatic food crop, aquatic nonfood, or aquatic impact uses.

11. Forestry Dissipation Studies. No data were reviewed; however, no data are required because fenamiphos has no forestry uses.

12. Long-term Field Dissipation Studies. No data were reviewed. The data requirement is deferred pending the receipt of acceptable field dissipation data.

13. Confined Accumulation Studies on Rotational Crops. Radio-labeled fenamiphos residues accumulated in mustard, sugar beets, and a grain crop planted 31 and 115 days after formulated radio-labeled fenamiphos was applied at 6 lb ai/A to a loamy sand soil. Parent fenamiphos was not detected in any crop; two degradates, fenamiphos sulfoxide and fenamiphos sulfone were detected at 0.01-0.18 and 0.01-0.23 ppm, respectively in all crops. Radio-labeled fenamiphos residues dissipated with a half-life of 308 to 328 days in the loamy sand soil. This study does not fulfill data requirements because the test substance was not analytical grade, residues in the soil were not characterized, residues in the crops were not adequately characterzied and meteorological data were inadequate. Therefore, data on the accumulation of fenamiphos in confined rotational crops are required.

14. Field Accumulation Studies on Rotational Crops. Fenamiphos residues were not detected in rotational radish, snap beans, or sorghum planted approximately 364 days after fenamiphos was applied at 1.5 and 3.0 lb ai/A to silty clay loam soil. Fenamiphos residues were $\leq$0.06, $\leq$0.03, 0.01, and <0.01 in mature rotational crops (turnips, blackeyed peas, and corn) planted approximately 30, 90, 120, and 364 days, respectively, after fenamiphos was applied at 1.5 to 6.0 lb ai/A to sandy soil. This study does not fulfill data requirements because the test substance was not characterized, the analytical method was nonspecific, residues in soil and crops were not characterized, and residues in the soil were not analyzed at the time of treatment. Data on the accumulation of fenamiphos in field rotational crops are required.

15. Accumulation Studies on Irrigated Crops. Data on the accumulation of fenamiphos in irrigated crops is required.

16. Accumulation Studies in Fish. The one study reviewed is inadequate. Data on the accumulation on fenamiphos in fish are required.

17. Field Accumulation Studies on Aquatic Nontarget Organisms. No data were reviewed; however, no data are required because fenamiphos has no forestry, aquatic noncrop, or aquatic impact use.

18. Groundwater. The potential for fenamiphos to reach ground water cannot be determined at this time. Of the seven studies required under the Groundwater Data Call-In, only two, hydrolysis and photodegradation in water, met guideline requirements. The Agency will evaluate the potential of fenamiphos to contaminate ground water after it has received and evaluated the following required data: photodegradation in air, aerobic and anaerobic metabolism, mobility, and field dissipation. The sulfoxide and sulfone metabolites of fenamiphos are included in the National Survey for Pesticides in Drinking Water, in lieu of parent fenamiphos, as the parent readily degrades.

Ecological Effects. Available data are insufficient to completely evaluate the ecological effects of fenamiphos. Data as set forth in Appendix I, Table A are either required or reserved pending further evaluation. The following conclusions can be made based on available data.

1. Toxicity to Birds and Mammals.

Technical Fenamiphos. Fenamiphos can be characterized as very highly toxic to the bobwhite quail (LD_{50} 1.6 mg/kg, LC_{50} 38 ppm) and highly toxic to the mallard duck (LC_{50} 316 ppm). Results of a bobwhite quail reproductive study demonstrated that dietary exposure of 8 ppm reduced chick survival by 31 percent with a NOEL of 2 ppm. Results of a mallard duck reproductive study demonstrated that dietary exposure of 16 ppm reduced feed consumption and egg production with a NOEL of 8 ppm. These data indicate that fenamiphos causes some reproductive impairment in both upland game birds and waterfowl at exposure levels of 2 and 8 ppm, respectively.

Granular 15 G. Applications of Nemacur® 15G at a rate of 134 lbs. ai/acre to turf, without irrigation, resulted in 70 and 15 percent mortality to English sparrows and bobwhite quail, respectively, when these birds were penned on the treated area. Even with 1/2 inch irrigation immediately following application, 50 percent of the English sparrows penned on treated plots died. Little or no hazard to penned birds was reported when Nemacur® 15G was both soil incorporated and unincorporated after band application (27 oz. formulation/1,000 feet of row) and incorporated after broadcast treatment (40 lb. formulation/acre). Results of these studies suggest that soil incorporation of granules reduces hazards to avian species.

Emulsifiable Concentrate (35%). Applications of Nemacur® 3 (35% SC) at rates of 6, 10, and 20 lbs. ai/acre and soil incorporated 2 to 3 inches resulted in approximately 10% mortality to bobwhite quail. In another small pen study with pheasants and rice birds, application of Nemacur® 3 at 5 lb. ai/acre on pineapples, resulted in approximately 25% mortality to the rice birds. Both significant avian and mammalian mortality was reported when 26 acres of orchard were sprayed with Nemacur® 3 at a rate of 23.5 lbs. ai/acre without soil incorporation.

Results of the above studies suggest that soil incorporation and/or irrigation will somewhat reduce hazards to non-target avian and mammalian species.

Because of study design deficiencies, none of the field studies discussed above fulfills the data requirements. A terrestrial field study is being required to determine if the hazard indicated by these laboratory and field studies are below the levels of concern for mammalian and avian species under actual use conditions (Appendix I, Table A).

2. Toxicity to Fish, Aquatic Invertebrates, and Estuarine/Marine Organisms.

Technical Fenamiphos. The lowest 96-hour LC_{50} for bluegill sunfish was determined to be 9.6 ppb, while the lowest 96-hour LC_{50} for rainbow trout was 72.1 ppb. These data suggest that fenamiphos is very highly toxic to both warm and cold water fish. The lowest 96-hour LC_{50}s for the bluegill sunfish for the two major degradates of the parent material were determined to be 2,000 and 1.173 ppb for the sulfoxide and sulfone group. The major metabolites of fenamiphos are considered to be moderately toxic to warm water fish.

Granular 15 G. One study, involving two fish species, was conducted using the 15G formulation. The 96-hour LC_{50} values were determined to be 151 and 563 ppb for the bluegill sunfish and rainbow trout, respectively. Based on the LC_{50} values listed above, the 15G formulation appears to be less toxic than the technical but still highly toxic to both warm and cold water fish.

The following additional studies are being required: an acute LC_{50} for fish using the 21 and 35% spray concentrate products; an acute LC_{50} for freshwater invertebrates using the technical and formulated products; an acute LC_{50} for estuarine and marine organisms; fish early life stage; fish life cycle; aquatic invertebrate life cycle; acquatic organism accumulation; and simulated and actual field testing of aquatic organisms (Appendix I, Table A).

3. Ecological Effects Hazard Assessment. Because of the ecotoxicological and environmental fate data gaps, there are insufficient data to fully assess the direct and indirect hazards of fenamiphos to nontarget fish and wildlife species. However, there are sufficient data to make certain preliminary statements about the acute and chronic hazards of fenamiphos to these species.

a. Terrestrial Hazard Assessment.

(1). Granular Formulation. Exposed fenamiphos granules pose a hazard because of their high toxicity to both mammalian and avian species. Field studies conducted with fenamiphos have documented that non-target birds and mammals can ingest lethal doses of granular pesticides during the course of their normal feeding activities. Agency-sponsored field studies also indicate that bird species which typically forage the soil for food or grit may also be exposed to soil incorporated granules. (Also, the use of sprinkler irrigation, to incorporate granules, may result in high levels of fenamiphos being concentrated in small puddles or wet spots which may also pose hazards to nontargets when they are drinking).

The hazards to nontarget mammalian and avian species posed by granular fenamiphos (15G) are based on the maximum application rates of 66 to 133 pounds formulated product (9.9 to 20.0 lb ai/A) per acre to tobacco, fruit trees, and ornamentals (soil and turf) and the LD_{50} for the most sensitive organisms tested. Label directions call for the 15G formulation to be soil incorporated 2 to 4 inches deep or irrigated into the soil immediately following application.

Although soil incorporation may reduce the potential for nontarget exposure, it does not eliminate it. Studies have shown that even with the most modern equipment, some granules still remain on the surface. Erbach and Tollerfson (1981) using commercially available equipment found that 5 percent of the granules applied remained on the soil surface. In another study, counts conducted immediately after incorporation revealed that both row areas (x = 70 granules/sq ft) and end row turn areas (x = 344 granules/sq ft) contained large numbers of exposed granules.

One way of assessing the potential for this hazard, under field conditions, is to compare the amount of toxicant available on a square foot basis with the acute oral LD_{50} value(s) for the species likely to be exposed. The closer the value is to the LD_{50} the greater the degree of hazard. Support for this approach can be found in the literature. Dewitt (1966) after conducting a quail field study concluded, "losses of birds may be expected if the quantity of toxicant per square foot equals or exceeds the quantity causing deaths of quail in short term feeding tests." Additional support is provided by Tucker (1972) who has reported that field kills have occurred in many instances when the amount of toxicant applied per acre exceeded 50,000 LD_{50}s (equal to approximately 1 LD_{50} per square foot).

Using the recommended application rate of 133 lb product/acre (95 percent soil incorporation assumed) and the average weight of one granule, 0.093 mg, the number of granules per square foot has been calculated to be 745 granules (10.43 mg ai) per square foot (Table 2).

(a). Avian Hazards. The primary routes of exposure to avian species are expected to be from the ingestion of granules and grit and drinking contaminated water. Based upon the acute oral LD_{50} value for bobwhite quail (16.0 mg/kg of 15G) and the average weight of the 15G granule (.093 mg), the number of granules equivalent to the LD_{50} values for six avian species has been determined (Table 3).

When these values are compared to the average number of granules per sq. ft. resulting from the maximum application rate, 745 granules/sq. ft. (Table 3), it appears that there is little margin for safety especially for small birds that forage for food or grit on the soil surface. In the case of the bobwhite quail which has the largest LD_{50} value of the six species in the table (equivalent to 34.4 granules), the average

TABLE 2

AVIAN TOXICITY/USE RATE CORRELATION

Nemacur® 15G (15% AI GRANULAR FORMULATION)
APPLICATION RATE OF 20 LB AI/ACRE (95% SOIL INCORPORATION ASSUMED = 1 LB AI/ACRE)

Organism	Body Weight (g)	LD$_{50}$ (mg prod/ kg)	LD$_{50}$ (mg prod/ animal) 1/	Quantity of Product/ Sq. Ft. 2/	Lethal No. of 15G Granules Required to Equal LD$_{50}$ 3/	No of granules/ Sq. Ft. 4/	LD$_{50}$ Equivalents/ Sq. ft. 5/
Bobwhite quail	200	16.0 mg prod/kg (2.4 mg ai/kg)	3.2 mg prod/ animal	69.3 mg	34.4	745	21.7
House sparrow	20	16.0 mg prod/kg (2.4 mg ai/kg)	0.32 mg prod/ animal	69.3 mg	3.4	745	217.0
Redwinged blackbird	50	16.0 mg prod/kg (2.4 mg ai/kg)	0.80 mg prod/ animal	69.3 mg	8.6	745	86.6

Calculation for the Bobwhite Quail

1/ LD$_{50}$ = 16.0 mg/kg prod x .2 kg = 3.2 mg prod/animal
2/ (133 lb prod/acre) x (454,000 mg/lb) = 60,382,000 mg prod/A
(60,382,000 mg/prod/A)/(43,560 ft^2/A) = 1386 mg prod/ft^2 x .05 = 69. 3 mg. prod/ft.^{2}
3/ (3.2 mg prod/animal)/(.093 mg/granule) = 34.4 granules/animal
4/ (69.3 mg prod/ft^2)/(0.093 mg/granule) = 745 granules/ft^2
5/ (69.3 mg prod/ft^2)/(3.2 mg prod/animal) = 21.7 LD$_{50}$ equivalents/ft^2
or (145 granules/sq ft)/(34.4 granules/LD$_{50}$) = 21.7 LD$_{50}$ equivalents/ft^2

TABLE 3
NEMACUR® 15G (15 % AI)
HAZARD TO SIX SPECIES OF NONTARGET BIRDS1/

Species	Body Weight (g)	LD_{50} as Mg(15G)/2/ Animal3/	Number of (15G) Granules Equal to LD_{50}4/
Bobwhite (adult)	200	3.20	34.4
Bobwhite (14-day)	30	0.48	5.1
Robin	80	1.28	14.0
Mourning dove	100	1.60	17.2
House sparrow	20	0.32	3.4
Redwing blackbird	50	.80	8.6
Grasshopper sparrow	13.9	.22	2.3

1/ Utilizing bobwhite quail LD_{50} of 16.0 mg/kg (15G) or 2.4 mg ai/kg (E. Hill, Patuxant Wildlife Research Center-Personal Communication).

2/ Weight of one 15G granule = 0.093 mg.

3/ 16.0 mg/kg (15G) x .2 kg = 3.2 mg/animal (15G) (LD_{50} for 15G to bobwhite quail on per body weight basis). All other values in this column based on the assumption that each organism has the same sensitivity as the bobwhite quail (i.e., LD_{50} for each organism is 16 mg/kg (15G).

4/ Number of 15G granules Required to equal LD_{50} = $\frac{3.2\text{ mg/animal (15G)}}{.093\text{ granule wt}}$ = 34.4

or

LD_{50} = 16 mg/kg (15G) x 15% = 2.4 mg ai/kg.
.2 kg x 2.4 mg ai/kg = .48 mg ai/animal

Number of granules (based on ai) required to equal LD_{50} = $\frac{.48\text{ mg ai/animal}}{.014\text{ mg (granule wt)}}$ = 34.4

number of granules per square foot equals 21.7 LD_{50} values, suggesting a very high degree of hazard. Again, these values suggest that the smaller birds, for example the house sparrow (with 217 LD_{50} equivalents per square foot), are at the greatest degree of risk. Although these calculations clearly indicate that this level of exposure may put birds at risk, further exposure analysis cannot be made without additional data; therefore simulated and actual field testing for birds is being required via this Registration Standard so that an accurate determination of risk can be made.

The Agency has also compared the potential toxicity of fenamiphos to restricted use criteria. The avian acute oral LD_{50} of 16.0 mg(15G)/kg for the bobwhite quail exceeds the Agency's proposed restricted use criteria for hazard to avian species of 50 mg/kg for granular products (U.S.E.P.A., "Hazard Evaluation Division, Standard Evaluation Procedure", EPA-540/9-85-001, p. 57, June 1986).

In addition, fenamiphos exceeds the restricted use criteria for avian species set forth in 40 CFR 162.11(c)(2)(iii)(B); exposure exceeds 1/5 the subacute dietary LC_{50} for the bobwhite quail. The subacute dietary LC_{50} of 179 ppm was calculated from the acute oral LD_{50} of 16.0 mg/kg for the 15G formulated product and food consumption and body weight data. The formula for calculating the LC_{50} is as follows:

Calculated LC_{50} = LD_{50}/(food consumption/body weight)

The 15G formulation contains 150,000 ppm fenamiphos; this dietary exposure far exceeds 1/5 the LC_{50} (179/5).

Finally, fenamiphos exceeds the restricted use criteria for non-target organisms outlined in 40 CFR 162.11(c)(2)(iii)(D). As discussed above under "Toxicity to Birds", the 15G formulation has resulted in mortality to English sparrows and bobwhite quail, thus exceeding the criteria of "...minor or no discernible adverse effects...".

(b). Mammalian Hazards. Possible routes of exposure to mammals from granulated formulations are from ingestion of granules, feeding on contaminated vegetation/ invertebrates or drinking contaminated water. Based on body weight and acute oral toxicity data, the number of granules equivalent to an LD_{50} for four species of mammals (Rat, Eastern Cottontail, Grey Squirrel, and Delmarva Fox), known to frequent agricultural areas, have been calculated (Table 4).

The average number of granules per square foot, 745, exceeds the LD_{50} for all but one of the four species, the Eastern cottontail. In the case of the rat, the number of granules per square foot exceeds the LD_{50} by 2.6 times. These data suggest that in terms of the available LD_{50} equivalents/sq. ft., small mammals are at a greater risk than large mammals and that very small rodents such as Microtus, Peromyscus, and Reithrodontomys are very likely to be exposed to lethal levels of fenamiphos from the 15G formulation.

Laboratory studies have shown that the sulfoxide is as toxic as the parent material. Environmental fate data show that fenamiphos and its metabolites are picked up systemically by plants and that sulfoxide residue may be present in certain soil for up to 2 years after application. These data suggest that small mammals feeding on contaminated vegetation are also likely to be exposed to fenamiphos and/or its metabolites. This is another issue that should be explored under simulated and actual field conditions.

The above discussion clearly indicates that mammals can be potentially exposed to fenamiphos either from ingestion of granules or from feeding on contaminated vegetation at levels that may put them at risk. Further exposure analyses cannot be made without additional data; therefore simulated and actual field testing for mammals are being required via this Registration Standard so that an accurate determination of risk can be made.

TABLE 4
MAMMALIAN SPECIES SENSITIVITY PROFILE [1]
NEMACUR® 15G (15% ai)
HAZARD TO FOUR SPECIES OF NONTARGET MAMMALS

Species	Body Weight (g)	LD_{50} as Mg ai/[2] Animal[3]	Number of Granules Equal to		Multiples of[7] LD_{50} Equivalents/ Sq. Ft.
			LD_{50}[4] 15G	1/5th LD_{50}[5] 15G	
Rat					
Adult	400	4.0	286	57	2.6
Eastern Cottontail					
Adult	1100	11.0	785.7	157.1	.94
Weaned young (20 days old)	85	0.85	60.7	12.1	12.3
Grey Squirrel					
Adult Female	520	5.2	371.4	74.2	2.0
Weaned Young (10 days old)	200	2.0	142.8	28.5	5.2
Delmarva Fox[6] Squirrel					
Adult Female	795	7.95	567.8	113.5	1.3
Weaned Young (8-10 wks old)	454	4.54	324.2	64.8	2.3

[1] Utilizing rat LD_{50} of 10 mg/kg ai.

[2] Weight of one 15G granule = 0.093 mg.
Weight of pesticide in one granule:
0.093 mg x 15% = 0.0139 mg ai/granule.

[3] Rat LD_{50} = 10 mg ai/kg
10 mg ai/kg x 0.4 kg body wt. = 4 mg ai/animal
(LD_{50} for Rat on per body weight basis)
All other values in this column based on the assumption that each organism has the same sensitivity as the rat (i.e., LD_{50} for each organism is 10 mg/kg ai).

[4] Number of 15G granules required to equal LD_{50} = $\frac{\text{4.0 mg ai/animal}}{\text{0.014 mg ai/granule}}$ = 286 granules

[5] Restricted Use classification criterion [40 CFR 162.11(c)(2)(iii)(B)].

[6] Weight data obtained via personal communication with Gary Taylor and Dr. Vagan Flyger of the Delmarva Fox Squirrel Recovery Team.

[7] 745(average number of granules/sq. ft)/number of granules equal to LD_{50}.

> Fenamiphos also exceeds the restricted use classification criterion for mammals (1/5 the acute oral LD_{50}) by 5 to 15 times for all four species in Table 4, indicating that unrestricted use of fenamiphos would constitute unreasonable adverse effects to mammals [40 CFR 162.11(c)(2)(iii)(A)].

(2). Emulsifiable Concentrate Formulation. As previously discussed, results of field studies suggest that the emulsifiable concentrate spray formulations, even when soil incorporated, cause mortality to both avian and mammalian species. The evidence also suggests, however, that soil incorporation does reduce hazard to some extent.

The extent to which avian species may be exposed and the degree of hazard from such exposure is shown in Tables 5 and 6. This hazard assessment for the 3EC formulation was based on exposure from the maximum application rate of 20 lb ai/A for fruit trees, and ornamentals (sod and turf), and dietary subacute toxicity data for the most sensitive species tested (bobwhite quail LC_{50} 38 ppm). Because label directions call for both broadcast and band applications to be soil incorporated immediately following application, the application rate of 20 lb ai/A has been adjusted to 1 lb ai/A to account for 95% soil incorporation. Table 5 presents the food factor calculations and correlation of total adjusted residues with calculated LC_{50} values for various species. Table 6 shows estimated dietary concentrations and the total estimated residues for eight species of nontarget birds.

Comparisons between expected dietary concentrations and LC_{50} values for eight species of nontarget birds suggest the following:

> 1. Small insectivorous birds such as the Carolina wren are likely to be exposed to the highest residues of fenamiphos and as such are the most susceptible to hazard.

2. Seed-eating birds such as the Mourning dove are likely to be exposed to the lowest residues of fenamiphos.

3. Residues of fenamiphos exceed NOELs for tested avian species (2 and 8 ppm for upland gamebirds and waterfowl, respectively) and suggest that reproductive impairment may occur under field conditions.

4. Mortality and or/other adverse effects associated with cholinesterase inhibition may occur to certain species regardless of size.

5. Total fenamiphos residues exceed the calculated subacute dietary LC_{50} for four species.

6. As the residue calculations in Table 6 assume 95% soil incorporation (which reduces the application rate of 20 lbs ai/ acre to estimated residues of 1 lb ai/acre), it is apparent that failure to adequately soil incorporate broadcast or band applications will greatly increase exposure and potential for adverse effects.

7. Total fenamiphos residues exceed 1/5 the calculated subacute dietary LC_{50} for all eight species (restricted use classification criterion, 40 CFR 162.11 (c)(2)(iii)(B)).

In addition, the emulsifiable concentrate formulation of fenamiphos exceeds the restricted use classification criteria as set forth in 40 CFR 162.11(c)(2)(iii)(D). Use of the 35% EC formulation resulted in significant avian and mammalian mortality, thus exceeding the criteria of "...minor or no discernible adverse effects...".

TABLE 5
CALCULATED LC_{50} VALUES FOR SEVEN SPECIES OF NONTARGET BIRDS[1]

Species[2]	Body Weight (gm)	Food Consumed (gm)	Food Cons./ Body Weight Percentage	Calculated LC_{50} (ppm) [3]
1. Bobwhite quail (Young)	30.0	6.0	20.0	38.0
2. Bobwhite quail (Adult)	170.00	15.20	8.94	85.0
3. Robin	81.10	8.11	10.00	75.9
4. Mourning dove	100.00	11.20	11.20	67.9
5. Eastern cowbird	50.00	7.00	14.00	54.3
6. Field sparrow	13.90	4.60	33.10	23.0
7. Grasshopper sparrow	13.90	4.60	33.10	23.0
8. Carolina wren	19.00	6.50 [4]	34.20 [4]	22.2

[1] All of the calculations for calculated LC_{50} (ppm), except for 38 ppm which is the reference LC_{50}, are based upon the assumption that each species has the same sensitivity to fenamiphos as bobwhite quail.

[2] All species considered are adult organisms, and the body weight and food consumption values are from Kenaga (1973), Nice (1938), and USDI, USFWS, Circular 199, 1964.

[3] These are the theoretical dietary levels which should cause 50% mortality (LC_{50}) using the assumption stated in (1) above (see Kenaga (1972 and 1973)). The procedure used is:

$$\frac{\text{Food Consumption}}{\text{Body Weight}} (\%) \times \begin{matrix}\text{Toxicant} \\ \text{Residue Level}\end{matrix} (\text{ppm}) = \begin{matrix}\text{Toxicant (mg/kg)} \\ \text{Body Weight/Day}\end{matrix}$$

[4] The food consumption value and, consequently, the food consumption/body weight (as %) value were developed from Kenaga (1973). In this article the food consumption values for a 19.0 gm three sparrow (*Spizella arborea*) are given as 7.11 and 5.95 gm, the mean equaling 6.53 gm. This value is considered suitable for use with the Carolina wren's body weight of 19.0 gm (from Nice 1938).

TABLE 6

DIETARY CONTAMINATION AND TOTAL ESTIMATED FENAMIPHOS RESIDUES FOR EIGHT SPECIES OF NON-TARGET BIRDS APPLICATION RATE 20 LBS AI/ACRE (95% SOIL INCORPORATION ASSUMED = 1 LB AI/ACRE)

Species	Calculated LC50 (ppm) [1]	1/5 Calculated LC50 (ppm) [2]	Food Consumed		Maximum Expected Residues (ppm) [4]		Maximum Adjusted Residues (ppm) [5]		Total Residues Both Plant And Animal
			Animal (%)	Plant	Animal	Plant	Animal	Plant	
Bobwhite quail (14-day)	38.0	7.6	80% Beetles Weevils Grasshoppers etc.	20% Seeds: Ragweed Lespedeza Corn etc.	58.0ppm(k) [7]	12.0ppm(k)	[8] 46.4ppm	[9] 2.4ppm	48.8ppm
Bobwhite quail (Adult)	85.0	17.0	27% Beetles Weavils Grasshoppers etc.	73% Seeds: Ragweed Lespedeza Corn etc.	58.0 ppm(k)	12.0 ppm(k)	15.7 ppm	8.8 ppm	24.5 ppm
Robin	75.9	15.2	40% Caterpillars Beetles Weevils Earthworms etc.	60% Seeds/ Fruits: Cherry Dogwood Holly	58.0 ppm(k)	12.0 ppm(k)	23.2 ppm	7.2 ppm	30.4 ppm
Mourning dove	67.9	13.6	0%	100% Seeds: Corn Pigweed etc.	58.0 ppm(k)	12.0 ppm(k)	0.0 ppm	12.0 ppm	12.0 ppm
Eastern cowbird (Adult)	54.3	10.9	52% Grasshoppers Beetles Caterpillars	48% Seeds: Bristlegrass Oats	58.0 ppm(k)	12.0 ppm(k)	30.1 ppm	5.8 ppm	35.9 ppm
Field sparrow (Adult)	23.0	4.6	51% Beetles Grasshoppers Caterpillars etc.	49% Seeds: Crabgrass Bristlegrass Panicgrass	58.0 ppm(k)	12.0 ppm(k)	29.6 ppm	5.9 ppm	35.5 ppm

TABLE 6 (continued)

DIETARY CONTAMINATION AND TOTAL ESTIMATED FENAMIPHOS RESIDUES FOR EIGHT SPECIES OF NON-TARGET BIRDS
APPLICATION RATE 20 LBS AI/ACRE (95% SOIL INCORPORATION ASSUMED = 1 LB AI/ACRE)

Species	Calculated LC50 (ppm) 1/	1/5 Calculated LC50 (ppm) 2/	Food Consumed		Maximum Expected Residues (ppm) 4/		Maximum Adjusted Residues (ppm) 5/		Total Residues Both Plant And Animal
			Animal (%)	Plant	Animal	Plant	Animal	Plant	
Grasshopper sparrow (Adult)	23.0	4.6	61% Grasshoppers Caterpillars Ants etc.	39% Seeds: Bristlegrass Ragweed Knotweed etc.	58.0 ppm(k)	12.0 ppm (k)	35.3 ppm	4.7 ppm	40.0 ppm
Carolina wren (Adult)	22.2	4.4	99% Ants Flies Milipedes etc.	1% Seeds Poison Ivy Pine Oaks etc.	58.0 ppm(k)	12.0 ppm(k)	57.4 ppm	.1 ppm	57.5 ppm

FOOTNOTES:

1/ Refer to Table 5 (Footnote 6) for an explanation of how the "calculated LC_{50}'s" were obtained.

2/ Restricted Use classification criteria [40 CFR 162.11(c)(2)(iii)(B)].

3/ This information is taken from Martin, Alexander C. et al., American Wildlife and Plants: A Guide Inc., NY 1951.

4/ Based upon a 1.0 lb active ingredient per acre (after soil incorporation) application to expected food times using the following references:

a. Hoerger, F.D.; Kenaga, E.E. Pesticide Residues on Plants. Correlation of Representative Data in the Environment. Environmental Quality, Academic Press, New York, I: 9-28, 1972.

TABLE 6 (continued)
DIETARY CONTAMINATION AND TOTAL ESTIMATED FENAMIPHOS RESIDUES FOR EIGHT SPECIES OF NON-TARGET BIRDS

FOOTNOTES (Continued)

b. Kenaga, E.E. Factors to be Considered in the Evaluation of the Toxicity of Pesticides to Bird and Safety, Academic Press, NY, II: 166-181, 1973.

5/ Residue values adjusted to reflect percentage of animal/plant matter consumed. Examples:

a. Bobwhite Quail, Adults:

58.0 ppm x 0.27 (27%) = 15.7 ppm
12.0 ppm x 0.73 (73%) = 8.8 ppm

b. Robin, Adult:

58.0 ppm x 0.40 (40%) = 23.2 ppm
12.0 ppm x 0.60 (60%) = 7.2 ppm

6/ Reflects total residues expected in the diet: animal or plant alone or a total of animal and plant food times. Examples:

a. Robin, Adult:

23.2 + 7.2 = 30.4 ppm total for animal and plant foods

b. Mourning Dove, Adult:

12.0 ppm total expected in food items consumed (i.e., 1.00 (100%) x 12.0 ppm = 12 ppm).

7/ (k) refers to maximum expected residues as per (4)(a), and (b) above.

8/ This is the maximum expected residue value for daily pesticide burden occurring from animal items.

9/ Daily pesticide burden occurring from ingested plant items.

b. Aquatic Hazard Assessment. Because fenamiphos has been characterized as very highly toxic to both cold and warm water fish species, the Agency is particularly concerned about the direct and indirect hazard that this material may pose to aquatic environments.

The terrestrial food crop uses where aquatic contamination is of primary concern are citrus, nonbearing fruit trees and tobacco where drift, runoff, and soil erosion of fenamiphos to lakes, streams, ponds, and other bodies of water and wetlands may occur. Obviously, the greatest potential for hazard to fish would occur if, during treatment, fenamiphos was directly applied to aquatic environments. There are no registered uses for direct application to water. However, such a circumstance could easily occur if fenamiphos were aerially applied as a broadcast soil treatment to fields where citrus, orchards, and tobacco are to be planted; and where interconnected waterways such as ditches, canals, creeks, streams, and ponds are used for irrigational purposes. Ground application would, for the most part, preclude any direct application to wetland areas. However, contamination could still occur from runoff.

Table 7 shows the estimated environmental concentrations of fenamiphos that could occur from direct application to water at the maximum accepted rate for three sites: citrus, fruit trees, and tobacco. Comparing the 96-hour bluegill sunfish LC_{50} of 9.6 ppb, the estimated exposures suggest that direct application of fenamiphos to lentic (sluggish) bodies of water (worst case situation) will result in residues in six inches of water that exceed 1/10th the LC_{50} by 1,250 times (1200ppb/0.96 ppb) and will most likely cause significant adverse effects. One-tenth the LC_{50} for aquatic organisms is the criteria for restricted use classification as specified in 40 CFR 162.11(c)(2)(iii)(C).

Table 8 shows the estimated environmental concentrations of fenamiphos in runoff for both lentic (sluggish) and lotic (actively moving) environments. EECs for fenamiphos from runoff have been determined for both lentic and lotic environments using the EXAMS II (Exposure Analysis Modeling System). To determine these EECs, the amount of runoff from a 10 hectare tobacco field (i.e., unit of runoff/acre from SWRRB x 10) was loaded into a Georgia pond (lentic)/ stream (lotic) scenario to simulate the fate of fenamiphos in a Georgia aquatic system. The Georgia pond-stream scenario consists of a one hectare farm pond, 2 meters-deep, that is surrounded by a 10 hectare drainage basin and drains into two streams. One is short (100 meters-long, 3 meters-wide and .05 meter -deep), and one is long 300 meters-long, 3 meters-wide, and .05 meter-deepr). EECs were based on an application rate of 20 lbs ai/A, soil incorporated (2-4") and/or watered-in (95% incorporation assumed).

Comparison of fish toxicity data and the EEC's in Table 8 suggest that nontarget fish indigenous to small ponds and streams will be exposed to fenamiphos residues in runoff (worse case situation) that are above the LC_{50} value (9.6 ppb) and restricted use classification criteria (1/10 LC50 = .96 ppb) and will most likely cause significant adverse effects.

In order to accurately determine the potential exposure and toxicity of fenamiphos to aquatic environments the Agency is requiring the aquatic toxicity tests listed in Appendix I, Table A of this standard which include simulated and actual field testing of aquatic organisms.

TABLE 7
ESTIMATED ENVIRONMENTAL CONCENTRATIONS[a] (EECs) (PPM) OF FENAMIPHOS IN WATER CONTAMINATED BY DIRECT APPLICATION

Crop	Application Rate (lb. ai/A)	Water Depth (in.)	Concentration[b] (ppm)
Fruit trees (bearing)	20.0	0.5	14.7
Citrus (bearing)	20.0	0.5	14.7
Tobacco	6.0	0.5	4.4
Fruit trees (bearing)	20.0	1.0	7.4
Citrus (bearing)	20.0	1.0	7.4
Tobacco	6.0	1.0	2.2
Fruit trees (bearing)	20.0	6.0	1.2
Citrus (bearing)	20.0	6.0	1.2
Tobacco	6.0	6.0	0.4

a/ Estimates are based upon the maximum application rate, aerially applied as a broadcast, preplant soil treatment.

b/ The concentration values shown are based upon a nomograph developed by DeWitt at the Patuxent Wildlife Research Center at Patuxent, Maryland.

TABLE 8
ESTIMATED ENVIRONMENTAL CONCENTRATIONS (EECs) (PPB)[a] OF FENAMIPHOS IN LENTIC AND LOTIC SCENARIOS FROM RUNOFF

	Concentration		
	Lentic	Lotic	
	Pond (ppb)	Stream I (ppb)	Stream II (ppb)
Soil Incorporation (2-4")			
a) 1% runoff	14.55	10.45	7.25
b) 5% runoff	72.8	52.27	36.25
Watered-in			
a) 1% runoff	112.0	80.42	55.78
b) 5% runoff	560.0	402.0	279.0

a/ EECs were based on an application rate of 20 lbs ai/A, soil incorporated (2-4") and/or watered-in (95% incorporation assumed).

c. Endangered Species Hazard Assessment.

1). EPA has consulted with the Office of Endangered Species of the Fish and Wildlife Service concerning the potential adverse effects on endangered and threatened species for the cotton and soybean uses of fenamiphos. OES issued biological opinions which found that these uses jeopardize the survival of the following species.

****

Cotton Cluster

Alabama cavefish
Attwater's greater prairie chicken
Bayou darter
Comanche springs pupfish
Foutain darter
Gila topminnow
Houston toad
Leopard darter
Mussels
Pecos gambusia
San Marcos gambusia
Slackwater darter

Soybean Cluster

Attwater's greater prairie chicken
Kern primrose sphinx moth 1/
Mussels
Scioto madtom
Slackwater darter

1/ California label only. Preplant soil treatment may result in minimal exposure to this insect.

****

The Agency has determined that the Endangered Species labeling contained in Section IV.D. of this Registration Standard is necessary to prevent unreasonable adverse effects to endangered or threatened species.

Reentry Considerations. Toxicity and exposure criteria are set forth in 40 CFR.158. If a chemical meets the specified criteria, reentry data are required.

Fenamiphos meets the toxicity criteria in that the technical grade of the active ingredient has an acute dermal toxicity of less than 200 mg/kg body weight, an acute inhalation toxicity of less than 200 mg/m^3 for a one-hour exposure, and an acute oral toxicity of less than 50 mg/kg body weight.

Fenamiphos also meets the exposure criteria in that it is registered for use on crops where current agricultural practices include human tasks which involve substantial exposure to residues of the pesticide. An interim 48-hour reentry interval is being imposed until adequate data have been submitted and evaluated.

Product Chemistry. The Agency has evaluated data which identify the ingredients, materials, and manufacturing process and discuss the physical and chemical properties of fenamiphos. Additional product chemistry data as identified in Appendix I, Tables A and B, are being required.

D. TOLERANCE REASSESSMENT

Tolerances have been established for residues of fenamiphos in a variety of raw agricultural commodities, in meat, fat and meat byproducts (40 CFR 180.349 [a] and [b]), and in processed food (21 CFR 193.463) and feed (21 CFR 561.232).

EPA has evaluated the residue and toxicology data supporting tolerances, and has made the following regulatory determinations:

•Whether the current tolerances and food additive regulations are sufficient to cover the actual residues resulting from use (including uses registered under FIFRA sec. 24(c) and intrastate uses).

•Whether group tolerances can be established in accordance with 40 CFR 180.34(f).

•Whether, in the absence of tolerances, restrictions on use, grazing, or feeding of treated commodities are necessary.

•Whether the tolerances are expressed accurately and in current terminology.

The regulatory determinations resulting from EPA's review are set out in Section IV.A. of this document, Regulatory Positions and Rationales.

1. Residue Data.

The residue data reviewed in support of these tolerances include the following:

a. Data on the nature of the residues in both plants and animals, including identification of major metabolites and degradates of fenamiphos. The metabolites of fenamiphos are fenamiphos sulfoxide (FSO), fenamiphos sulfone (FSO_2), des-isopropyl fenamiphos (DIF), des-isopropyl fenamiphos sulfoxide (DIFSO), fenamiphos sulfoxide phenol (FSOP), fenamiphos sulfone phenol (FSO_2P), and fenamiphos phenol (FP). Tolerances for residues of fenamiphos in food items derived from plants are currently expressed in terms of the combined residues of fenamiphos and its cholinesterase-inhibiting metabolites, fenamiphos sulfoxide and fenamiphos sulfone. Tolerances for residues of fenamiphos in food items derived from animals are expressed in terms of the combined residues of fenamiphos and its sulfoxide and sulfone as well as des-isopropyl fenamiphos, des-isopropyl fenamiphos sulfoxide and des-isopropyl fenamiphos sulfone.

b. Radiolabeled studies on the uptake, translocation and metabolism of fenamiphos in plants show that metabolic pathways involve oxidation of fenamiphos to fenamiphos sulfoxide and/or fenamiphos sulfone and subsequent hydrolysis to fenamiphos sulfoxide phenol and fenamiphos sulfone phenol and formation of glucoside and other conjugates. Although the phenols are present as significant portions of the total residue in plants, they are not currently included in the tolerance expression because the Agency has no concern regarding their toxicological significance at this time.

c. Radiolabeled studies on the metabolism and translocation of fenamiphos in cows, rats, chickens, and swine show that the metabolism of fenamiphos in poultry (including eggs) and ruminants (including milk) is not adequately understood. In addition to the known plant metabolites, des-isopropyl fenamiphos and des-isopropyl fenamiphos sulfoxide have been found in ruminant tissues and milk after dosing with fenamiphos sulfoxide.

There are deficiencies in available hen, ruminant, and swine metabolism studies. Therefore, metabolism studies utilizing ruminants and poultry in which ring-labeled [^{14}C] fenamiphos is administered are being required. In addition tissue samples from these studies must be analyzed using current enforcement methods. Should the metabolism of fenamiphos in ruminants or poultry be found to differ significantly from that in rats, additional swine metabolism studies may be required.

d. Analytical methodology for determining the levels of residues of fenamiphos in plants and animals. Residues of fenamiphos sulfoxide and fenamiphos sulfone in or on plant and animal commodities and of des-isopropyl fenamiphos, des-isopropyl fenamiphos sulfoxide, and des-isopropyl fenamiphos sulfone in or on animal commodities must be subjected to analysis by multiresidue protocols available from the National Technical Information Service (NTIS). Additional methods, validation data and residue data may be required if metabolism studies indicate additional metabolites of toxicological concern in animals.

e. Storage stability data. Fenamiphos, fenamiphos sulfoxide, and fenamiphos sulfone are stable in frozen plant commodities stored up to 1,086 days. Additional storage stability data for residues in muscle, fat, liver, kidney, milk, and eggs are necessary because the available data indicate poor stability in animal tissues and products after 64-75 days of frozen storage. Data on storage intervals and conditions of storage of previously submitted samples must be submitted and accompanied by fortification recovery data for all animal commodity samples and any plant samples stored longer than 3 years.

It should be noted that the nature of the residue in animals has not been adequately described. If the requested metabolism data indicate the presence of additional residues of toxicological concern in animal commodities, data depicting the stability of such residues in storage will be required.

f. Data on the magnitude and levels of residues of fenamiphos in individual raw agricultural commodities, animal products, and processed food and feed items. Sufficient data are available to ascertain the adequacy of the established tolerances for residues of fenamiphos in or on the following raw agricultural and processed commodities: brussels sprouts, cabbage, soybeans, grapefruit, lemons, limes, oranges, tangerines, dried citrus pulp, citrus oil, citrus molasses, apples, dried apple pomace, cherries, peaches, grapes, raisins, raisin waste, raspberries, asparagus, cottonseed, okra, peanuts, and pineapples.

Insufficient data are available to ascertain the adequacy of the established feed additive tolerances for residues in dried grape pomace and pineapple bran. Also, processing studies are required for the following commodities: soybeans, grapes (juice and dried pomace only), cocoa beans, cottonseed, peanuts, meat, and milk,

Sufficient documentation is not available to ascertain the adequacy of the established tolerances for fenamiphos residues in or on garlic, bananas, and cocoa beans imported into the U.S. Also, additional residue data are needed for cocoa beans.

2. Toxicology Data.

The toxicology data considered in support of the tolerances include:

2-year dog feeding study; NOEL = .025 mg/kg of animal body weight/day

The Acceptable Daily Intake (ADI) and Maximum Permissible Intake (MPI) are two ways of expressing the amount of a substance that the Agency believes, on the basis of the results of data from animal studies and the application of "safety" or "uncertainty" factors, may safely be ingested by humans without risk of non-oncogenic adverse health effects. The ADI is expressed in terms of milligrams (mg) of the substance per kilogram (kg) of body weight per day (mg/kg/day). The MPI, a related figure, is obtained by assuming a human body weight of 60 kg, and is expressed in terms of mg of substance per day (mg/day). The Agency has calculated a Provisional ADI (PADI) of 0.00025 mg/kg/day for fenamiphos due to the lack of an adequate teratology study. The MPI for fenamiphos is 0.015 mg/day.

The PADI for fenamiphos currently is based on the results from a 2-year dog feeding study, from which the Agency concluded that the no-observed-effect-level (NOEL) was seen at 1 ppm of the substance in the animals' diet, or 0.025 mg/kg of animal body weight/day. Cholinesterase inhibition was seen at all other dose levels, 2, 5, and 10 ppm. The PADI was derived by use of a safety factor of 100 to account for the lack of an adequate teratology study. The NOEL from the dog study, 0.025 mg/kg/day divided by this 100-fold factor, yields a human PADI of 0.00025 mg/kg/day. The MPI for a 60-kg human is 0.015 mg/day.

The theoretical maximum residue contribution (TMRC) is the theoretical maximum amount of residue of a pesticide that might be present in the human diet, based on assumptions the Agency makes about the average human daily intake of foods containing residues at the level of the established tolerances. The TMRC for the U.S. population average based on published tolerances only is 0.0020 mg/kg/day which occupies 812% of the PADI. Utilization of anticipated residues and percent of crop treated lowers this estimate to 0.00011 mg/kg/day which corresponds to 42% of the PADI.

Dietary exposures for 22 subgroups of the U.S. population have also been estimated. The two highest highest calculated exposures (published tolerances only) were non-nursing infants with a TMRC of 0.0067 mg/kg/day which occupies 2684% of the PADI, and children 1 to 6 years of age with a TMRC of 0.0056 mg/kg/day which occupies 2230% of the PADI. Utilization of anticipated residues and percent of crop treated lowers these estimates to 0.0003 mg/kg/day, which occupies 112% of the PADI, and 0.0002 mg/kg/day, which occupies 96% of the PADI, respectively. Since meat and milk contribute significantly to the TMRC, it is possible that the required processing studies that will demonstrate the effect of cooking meat and the pasteurization of milk or the production of infant formula on residue levels of fenamiphos and its metabolites, may lower the estimated dietary exposure for these two subgroups in particular in addition to the overall U.S. population.

Since the PADI is a provisional value, it is possible that resolution of the teratology data gap may allow for a lower uncertainty factor which will result in a higher ADI and consequently a lower percentage of the ADI occupied by the TMRC.

3. Tolerances issued.

Tolerances have been established for residues of fenamiphos in a variety of raw agricultural commodities (40 CFR 180.349 [a]), in meat, fat and meat byproducts (40 CFR 180.349 [b]), and in processed food (21 CFR 193.463) and feed (21 CFR 561.232).

There are no Mexican or Canadian tolerances for fenamiphos. To permit compatibility with Codex Maximum Residue Limits (MRLs), the Agency is; (1) reducing the tolerances for residues in or on brussels sprouts and cabbage from 0.1 to 0.05 ppm; (2) establishing a crop group tolerance of 0.5 ppm for residues in or on citrus fruit (with a concomitant revocation of the 0.6 ppm tolerances for residues in or on oranges, grapefruit, lemons, limes, and tangerines); and (3) increasing tolerances for residues in or on peanuts from 0.02 to 0.05 ppm.

In addition, the Agency is making the following determinations:

(1). "grape pomace" in the 21 CFR should be changed to "grape pomace dried", the appropriate definition for this commodity.

(2). a tolerance proposal of 0.1 ppm or feeding and grazing restrictions must be proposed for cotton forage.

(3). Special Local Need registrations [FIFRA Sec. 24(c)] permitting the use of fenamiphos as broadcast soil applications to nonbearing nut trees and pears must be canceled or supported by residue data to determine the appropriateness of the current nonfood classification.

(4). For tobacco, data depicting pyrolysis products derived from the active ingredient must be submitted.

Tolerances are pending for residues in or on carrots, sugar beet roots, dried pulp and tops, sweet potatoes, tomatoes, and dried tomato pulp, and cucurbit vegetables.

IV. REGULATORY POSITION AND RATIONALE

A. REGULATORY POSITIONS AND RATIONALES

Based on the review and evaluation of all available data on fenamiphos the Agency has made the following determinations. Where it is the Agency's position that label revisions are needed in order for a product to remain in compliance with FIFRA, specific language is set forth in Section D of this chapter.

1. The Agency will not, at this time, initiate a Special Review [40 CFR Part 154] of fenamiphos. After review and evaluation of the required studies for fish and wildlife the Agency will reconsider the possibility of a Special Review. Acceptable protocols for conducting the avian, mammalian, and fish field studies must be submitted within six months of the issuance of the standard and be accepted by the Agency before the initiation of field work. Annual progress reports must also be submitted for the duration of the study. The application rates used in these studies must be the lowest possible rates that are still efficacious as indicated by the required efficacy data (refer to Regulatory Position 3).

Rationale: Fenamiphos is very highly toxic to birds (LD_{50} 1.6 mg/kg) and mammals (LD_{50} 2.7 mg/kg) as well as to cold (LC_{50} 72.1 ppb) and warm water (LC_{50} 9.6 ppb) fish species.

Estimated environmental concentrations (EECs) of the granular formulation of fenamiphos exceed the acute oral LD_{50} for the most sensitive avian species tested, the bobwhite quail, and the estimated LD_{50} values for 5 other avian species. EECs also exceed the LD_{50} for the rat and the estimated LD_{50} values for two other mammalian species. EECs of the emulsifiable concentrate formulation indicate that fenamiphos residues exceed the calculated subacute dietary LC_{50} for four avian species.

Field studies using both granular and spray formulations of fenamiphos according to label directions have shown some avian and mammalian mortality. These studies also suggest that soil incorporation and/or irrigation immediately following application reduces hazards. However, because of design deficiencies these studies do not meet guideline requirements; therefore, a terrestrial field study is being required to determine if the hazards indicated by lab and field studies are below levels of concern for mammalian and avian species under actual use conditions.

Estimated environmental concentrations for water contaminated by aerial application to crops and for runoff exceed the LC_{50} values for bluegill sunfish, and therefore, would cause significant adverse effects. Thus, the following tests are being required to fully assess the potential exposure and toxicity of fenamiphos to aquatic environments: freshwater fish toxicity (on EPs), freshwater invertebrate acute toxicity (using the technical and EPs), estuarine and marine acute toxicity, fish early life stage testing, fish life cycle, aquatic invertebrate life cycle, aquatic organism accumulation, and simulated and actual field testing of aquatic organisms.

2. The Agency is requiring restricted use classification for all fenamiphos formulated products.

Rationale: Fenamiphos exceeds the restricted use criteria set forth in 40 CFR 162.11(c)(2)(ii) and (iii). Use of fenamiphos formulations has resulted in mortality to birds and mammals. Fenamiphos is acutely toxic to laboratory animals, Toxicity Category I, by the oral, dermal, and inhalation routes of exposure. It is also very highly toxic to birds as well as cold and warm water fish species. Use of fenamiphos exceeds the restricted use criteria for fish and wildlife; calculated residues exceed 1/5 the acute oral LD_{50} for mammals, 1/5 the subacute dietary LC_{50} for avian species, and 1/10 the acute LC_{50} for aquatic organisms. In addition, use of fenamiphos has resulted in mortality to birds and mammals. / Accordingly, the Agency has determined that the risks to humans, fish, and wildlife, associated with the unrestricted use of fenamiphos products, constitute unreasonable adverse effects. Restricting the use of all fenamiphos products will reduce exposure and the potential for acute toxicity. Field studies on birds, mammals, and aquatic organisms, are being required to determine actual exposure levels and potential hazard.

3. The Agency is requiring that efficacy data be submitted to support all currently registered application rates.

Rationale: EECs based on the maximum application rate exceed LD_{50} values for birds and mammals and the LC_{50} value for fish. Therefore, the Agency is requiring that efficacy data be submitted within six months of the issuance of the standard to support the current application rates. If such data indicate that rates could be lowered with minimal decrease in efficacy the Agency will require that all labels be revised to the lowest possible rates that are still efficacious. These labeling changes would reduce environmental concentrations of the pesticide while substantive data on the effects on fish and wildlife are being collected.

4. The Agency is requiring that all labels be revised as follows:

1). Directions for broadcast spray will be deleted for sites which currently have directions for both band and broadcast spray.

2). All labels will prohibit the use of mist sprayers and will direct applicators to use only coarse sprays directed at the soil to reduce the possibility of spray drift.

3). All labels will specifically prohibit aerial application.

Rationale; As stated above, EECs based on the maximum application rate exceed LD_{50} values for mammalian and avian species and the LC_{50} value for aquatic organisms. The above labeling changes would reduce environmental concentrations of the pesticide while substantive data on the effects of fenamiphos on fish and wildlife are being collected.

5. The Agency is requiring endangered species labeling on fenamiphos EPs registered for use on cotton and soybeans in accordance with Pesticide Registration (PR) Notice 87-5 (issued May 1, 1987). (Refer to Chapter IV, Section D of /this document, for exact language.)

Rationale: Fenamiphos was reviewed for endangered species implications. In order to protect endangered species from harm, endangered species labeling is required. (Refer to Chapter III, Section C of this document, for a list of the species).

6. The Agency is unable to fully assess the environmental fate of fenamiphos and is requiring the following studies: photodegradation (air), anaerobic and aerobic soil metabolism, leaching and adsorption/desorption, volatility (lab), soil dissipation, rotational crops (confined and field), fish accumulation, and spray drift studies.

Rationale: Except for a hydrolysis study and a photodegradation study in water, all the available environmental fate data do not meet the guideline standards for acceptable testing. These data are normally required under 40 CFR Part 158.130 and are necessary to assess the environmental fate and transport and potential exposure to fenamiphos.

7. The Agency will evaluate the potential of fenamiphos to contaminate ground water after it has received and evaluated additional required environmental fate data.

Rationale: The potential for fenamiphos to reach ground water cannot be determined at this time. Some existing studies, though deficient in some respects, show it does leach to some degree. Additional data are required to fully assess the potential for fenamiphos to reach ground water.

8. The Agency is unable to completely define the metabolism of fenamiphos and to fully assess its teratogenic potential; therefore, the Agency is requiring the submission of a rat metabolism study and teratology studies in two species.

Rationale: General metabolism and teratology studies are normally required by 40 CFR Part 158.135 for products with fenamiphos' use patterns. There are currently no metabolism studies or rat teratology studies available and the available rabbit teratology study does not meet guideline requirements.

9. Available residue chemistry and toxicology data are insufficient to permit the Agency to conduct a full tolerance reassessment.

Rationale: Data gaps exist for animal metabolism, storage stability, analytical methods, and magnitude of residues in some raw agricultural commodities and processed food and feed items. Thus, upon receipt of the data required in Table A, the Agency's conclusions with regard to the adequacy of established tolerances are subject to change.

10. The Agency is not requiring additional residue data on the following raw agricultural commodities or proceseed feed items: brussels sprouts, cabbage, soybeans, grapefruit, lemons, limes, oranges, tangerines, dried citrus pulp, citrus oil, citrus molasses, apples, dried apple pomace, cherries, peaches, grapes, raisins, raisin waste, raspberries, asparagus, cottonseed, okra, peanuts, and pineapples.

Rationale: The Agency has determined that the available residue data adequately support the established tolerances for these raw agricultural commodities.

11. The Agency is requiring English language translation of product labels for garlic, bananas, and cocoa beans imported into the U.S.

Rationale: Insufficient documentation is available to ascertain the adequacy of the established tolerances for fenamiphos residues in or on garlic, bananas, and cocoa beans imported into the U.S. The Agency will be able to determine from current English translation labels if overseas application rates result in residues that exceed established tolerances.

12. The Agency is requiring data to determine the pyrolysis products of fenamiphos in tobacco products and the level of residues in tobacco smoke.

Rationale: Residue data previously submitted for residues of fenamiphos in or on tobacco indicate that the combined residues of fenamiphos and its sulfoxide and sulfone in or on cured tobacco exceed 0.1 ppm following application at the registered rate. Therefore, the Agency is requiring these data to assess the human exposure to fenamiphos residues in tobacco products.

13. The Agency is; (1) reducing tolerances for residues in or on Brussels sprouts and cabbage from 0.1 to 0.05 ppm, (2) establishing a crop group tolerance of 0.5 ppm for residues in or on citrus fruit (with a concomitant revocation of the 0.6 ppm tolerance for residues in or on oranges, grapefruit, lemons, limes), and (3) increasing tolerances for residues in or on peanuts from .02 to .05 ppm.

Rationale: These actions will permit compatibility with CODEX MRLs.

14. The Agency is requiring the submission of residue data supporting broadcast soil application of fenamiphos to nonbearing nut trees and pears (FIFRA Section 24(c)).

Rationale: The data are required to assess the current non-food classification of this use. Alternatively, the registrant may cancel this use.

15. The Agency is requiring a tolerance proposal of 0.1 ppm for cotton forage.

Rationale: Based on available data the Agency has determined that a tolerance of 0.1 ppm would be appropriate. Alternatively, the registrant may amend use directions to include grazing and feeding restrictions for cotton forage.

16. The Agency is requiring reentry data for fenamiphos. In order to maintain compliance with FIFRA an interim 48-hour reentry interval requirement for fenamiphos must be placed on the labels of all fenamiphos end-use products until the required data are submitted and evaluated and any change in this interim reentry interval is announced.

Rationale: Fenamiphos meets both the acute toxicity and exposure criteria specified in 40 CFR 158.140 for reentry data. Until these data are received and evaluated an interim 48-hour reentry interval will serve to reduce exposure of field workers to this chemical.

17. While data gaps are being filled, currently registered manufacturing use products (MPs) and end use products (EPs) containing fenamiphos as the sole active ingredient may be sold, distributed, formulated and used, subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop additional data, as specified in the Data Appendices, in order to maintain existing registrations.

Rationale: Under FIFRA, the Agency does not normally cancel or withhold registration simply because data are missing or are inadequate (see FIFRA sec. 3(c)(2)(B) and 3(c)(7).

Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory changes are necessary.

B. CRITERIA FOR REGISTRATION

To be registered or reregistered under this Standard, products must contain fenamiphos as the sole active ingredient, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this section.

C. ACCEPTABLE RANGES AND LIMITS

1. Product Composition Standard

To be registered or reregistered under this Standard, manufacturing-use products (MPs) must contain fenamiphos as the sole active ingredient. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1%.

2. Acute Toxicity Limits

The Agency will consider registration of technical grade and manufacturing-use products containing fenamiphos provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

3. Use Patterns

To be registered under this Standard, manufacturing-use products may be labeled for formulation into end-use products only for the commodities listed below. The EPA Index to Pesticide Chemicals lists all registered uses, as well as approved maximum application rates and frequencies.

-Terrestrial, non-domestic, food uses on:
apples, asparagus, brussels sprouts, cabbage, cherries, citrus citrus, cotton, grapes, okra, peach, peanuts, pineapple, raspberry, soybeans

-Terrestrial, non-domestic, non-food uses on:

non-bearing orchards, nursery stock (forest trees and ornamentals), tobacco

D. LABELING

Products subject to the requirements of this Registration Standard may not be released for shipment after August 1, 1988, unless the product bears amended labeling which complies with the requirements of this Standard. [Exception: Endangered species labeling which must be on products released for shipment after February 1, 1988 and on all products after February 1, 1989 as specified in Pesticide Registration (PR) Notice 87-5.] After reviewing data to be submitted under this Standard, the Agency may impose additional label requirements.

Products subject to the requirements of this Registration Standard may not be distributed, sold, offered for sale, held for sale, shipped, delivered for shipment, or received and (having been so received) delivered or offered to be delivered by any person after August 1, 1988, unless the product bears amended labeling which complies with the requirements of this standard.

1. Manufacturing-Use Product Statements

a. Ingredients Statement

/ The ingredient statement for MPs must list the active ingredient as:

O-ethyl-O-(3-methyl-4-methyl-thiophenyl)isopropyl-phosphoramidate

b. Use Pattern Statements

All manufacturing-use products must state that they are intended for formulation into end-use products for acceptable use patterns. Labeling must specify sites, which are listed in Use Patterns, Section C.3. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in TABLE A for that use pattern.

c. Precautionary Statements

This pesticide is toxic to fish and wildlife. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this product is specifically identified and addressed in the NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

2. End-Use Product Statements

a. Ingredients Statement

The ingredient statement for EPs must list the active ingredient as:

O-ethyl-O-(3-methyl-4-methyl-thiophenyl)isopropyl-phosphoramidate

b. Precautionary Statements

RESTRICTED USE PESTICIDE
For sale to and use only by a certified applicator for uses authorized by his certification, or by persons under his direct supervision.

Do not reenter treated area for 48 hours unless appropriate protective clothing is worn.

USE ONLY WHEN WEARING THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT DURING MIXING/LOADING, APPLICATION, REPAIR AND CLEANING OF MIXING, LOADING AND APPLICATION EQUIPMENT, DISPOSAL OF THE PESTICIDE, AND EARLY REENTRY INTO TREATED AREAS: protective suit of one or two pieces covering all parts of the body except head, hand, and feet; chemical resistant gloves; chemical-resistant shoes (or chemical-resistant shoe covers or chemical-resistant boots); and a NIOSH- or MSHA- approved respirator. In addition, mixer/loaders must wear a chemical-resistant apron. During equipment repair and cleaning, the respirator need not be worn. During early reentry after sprays have dried or dust has settled and vapors have dispersed, the respirator need not be worn.

IF MIXING/LOADING IS PERFORMED USING A CLOSED SYSTEM, THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT MAY BE WORN AS AN ALTERNATIVE: long-sleeved shirt and long-legged pants; chemical-resistant gloves; chemical-resistant apron; shoes and socks. Goggles or face shield must be worn if the system is under pressure.

IF APPLICATION IS PERFORMED USING AN ENCLOSED CAB, THE FOLLOWING PROTECTIVE CLOTHING AND EQUIPMENT MAY BE WORN AS AN ALTERNATIVE: long-sleeved shirt and long-legged pants; shoes, and socks. Chemical-resistant gloves must be available in the cab and must be worn when exiting. This clothing is inadequate to protect you during equipment repair or cleaning, reentry, or pesticide disposal work.

IMPORTANT! If pesticide comes in contact with skin, wash off with soap and water. Always wash hands, face, and arms with soap and water before smoking, eating, drinking, or toileting.

AFTER WORK: Before removing gloves, wash them with soap and water. Take off all work clothes and shoes. Shower using soap and water. Wear clean clothes. Do not reuse contaminated clothing. Personal clothing worn during work must be laundered separately from household articles. Store protective clothing separately from personal clothing. Clean or launder protective clothing after each use. Respirators must be cleaned and filters replaced according to instructions included with the respirator. Protective clothing and equipment that becomes heavily contaminated or drenched must be destroyed according to state and local regulations. HEAVILY CONTAMINATED OR DRENCHED CLOTHING CANNOT BE ADEQUATELY DECONTAMINATED.

° Formulations other than granular:

This pesticide is toxic to fish and wildlife. Drift and runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water or wetlands (swamps, bog, marshes, and potholes). Do not contaminate water by cleaning of equipment or disposal of wastes.

Do not use mist sprayers. Use only coarse sprays directed at soil to eliminate spray drift.

Aerial application of this product is prohibited.

° Granular formulations:

This pesticide is toxic to fish and wildlife. Cover, incorporate, or pick up spilled granules at row ends or turn areas. Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water by cleaning of equipment or disposal of wastes.

The following information on endangered species must appear on the labeling of all EPs registered for use on soybeans and cotton. Statement "A" is to be used only on product labels if Statement "B" is not on the product label, but instead, in the product labeling. [EXCEPTIONS: Products used directly on humans or pets; in, on or around any structure, vehicle, article, surface, or area associated with the household, including but not limited to areas such as out-buildings, non-commercial greenhouses, pleasure boats, and recreational vehicles, or in any preschool or day care facility, and which are labled only for such uses are exempt from the labeling requirements to protect endangered species].

A. "Refer to product labeling for use restrictions to protect ENDANGERED SPECIES."

B. "ENDANGERED SPECIES RESTRICTIONS

The following restrictions apply to use of this product after February 1, 1988.

Before using this pesticide on cotton and soybeans in the counties listed below, you must obtain the PESTICIDE USE BULLETIN FOR PROTECTION OF ENDANGERED SPECIES for the county in which the product is to be used. The bulletin is available from your County Extension Agent, State Fish and Game Office or your pesticide dealer. Use of this product in a manner inconsistent with the PESTICIDE USE BULLETIN FOR PROTECTION OF ENDANGERED SPECIES is a violation of Federal laws."

ALABAMA
COLBERT, GREENE, JACKSON, LAMAR LAUDERDALE, LIMESTONE, MADISON, MARSHAL, MORGAN, PICKENS, AND SUMTER

ARIZONA
GRAHAM, MARICOPA, MOHAVE, PIMA, PINAL, AND SANTA CRUZ

ARKANSAS
BENTON, CLAY, CLARK, CROSS, LAWRENCE, LEE, POINSETTE, POLK, RANDOLPH, SHARP, AND ST. FRANCIS

CALIFORNIA
COLUSA, IMPERIAL, INYO, LOS ANGELES, MERCE, MODOC, ORANGE, RIVERSIDE, SAN BERNARDINO, SAN DIEGO, SANTA BARBARA, STANISLAUS, SUTTER, AND VENTURA

FLORIDA
ALACHUA, BAKER, BRADFORD, BREVARD, BROWARD, CHARLOTTE, CITRUS, CLAY, COLLIER, COLUMBIA, DADE, DE SOTO, DIXIE, DUVAL, FLAGLER, GADSDEN, GILCHREST, GLADES, HARDEE, HENDRY, HERNANDO, HIGHLANDS, HILLSBOROUGH, INDIAN RIVER, JEFFERSON, LAFAYETTE, LAKE, LEE, LEON, LEVY, MADISON, MANATEE, MARION, MARTIN, MONROE, NASSAU, ORANGE, OKEECHOBEE, OSCEOLA, PALM BEACH, PASCO, PINELLAS, POLK, PUTNAM, ST. JOHNS, ST. LUCIE, SARASOTA, SEMINOLE, SUMTER, SUWANNE, TAYLOR, UNION, VOLUSIA, AND WAKULIA

GEORGIA
BRANTLEY, BRYAN, BULLOCH, BURKE, CAMDEN, CANDLER, CHARLTON, CHATHAM, EFFINGHAM, EMANUEL, EVANS, GLASCOCK, GLYNN, JEFFERSON, JENKINS, JOHNSON, LIBERTY, LONG, MCINTOSH, PIERCE, RICHMOND, SCREVEN, WARE, WASHINGTON, AND WAYNE

KANSAS
CLARK, COMANCHE, MEADE, AND STAFFORD

KENTUCKY
BALLARD, BUTLER, EDMUNDSON, GREEN, HART, JACKSON, LAUREL, LIVINGSTON, MARSHALL, MCCRACKEN, MCCREARY PULASKI, ROCKCASTLE, TAYLOR, WARREN, AND WAYNE

MISSISSIPPI
CLAIBORNE, COPIAH, HINDS, ITAWAMBA, LOWNDES, MONROE, AND NOXUBEE

MISSOURI
BARRY, BENTON, CAMDEN, CHRISTIAN, DALLAS, GREENE, HICKORY, JASPER, LAWRENCE, MILLER, NEWTON, OSAGE, POLK, ST. CLAIR, STONE, AND WEBSTER

MONTANA
GARFIELD, MCCONE, SHERIDAN, AND VALLEY

NEBRASKA
BOYD, BROWN, BUFFALO, BUTLER, CASS, CEDAR, COLFAX, DAWSON, DODGE, DOUGLAS, HALL, HAMILTON, HOLT, HOWARD, KEARNEY, KEYA PAHA, KNOX, MERRICK, NANCE, PHELPS, PLATTE, POLK, ROCK, SARPY, AND SAUNDERS

NEVADA
    CLARK

NEW MEXICO
    CHAVES, DEBACA, AND EDDY

NORTH CAROLINA
    EDGECOMBE, NASH, AND PITT

NORTH DAKOTA
    BANSON, BOTTINEAU, BURKE, BURLEIGH, DIVIDE, DUNN, EDDY, EMMONS, FOSTER, KIDDER, LOGAN, MCHENRY, MCINTOSH, MCKENZIE, MCLEAN, MERCER, MORTON, MOUNTRAIL, NELSON, OLIVER, PIERCE, RAMSEY, RANVILLE, ROLETTE, SHERIDAN, SIOUX, STUTSMAN, TOWNER, WARD, WELLS, AND WILLIAMS

OHIO
    PICKAWAY

OKLAHOMA
    DELAWARE, MCCURTAIN, AND PUSHMATAHA

OREGON
    LAKE

SOUTH CAROLINA
    AIKEN, BARNWELL, BEAUFORT, BERKELY, CHARLESTON, COLLETON, DORCHESTER, GEORGETOWN, HAMPTON, HORRY, JASPER, AND MARION

SOUTH DAKOTA
    CLAY, HAAKON, HUGHS, POTTER, STANLEY, SULLY, UNION, WALWORTH, YANKTON, AND ZIEBACH

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submission or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

2. The data requirements listed in Tables A and B[2].

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-specific data applicable to manufacturing use products. The data in Tables A and B need not be submitted by a producer who is eligible for the formulator's exemption for that active ingredient.

Table C lists product-specific data applicable to end use products.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

The data requirements listed in Table A.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions upon use, composition, or packaging listed in Section IV.

2. If eligible for the formulator's exemption[3], the data requirements listed in Table C.

3. If not eligible for the formulator's exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

a. If not eligible for the formulator's exemption, the date requirements listed in Tables A and C.

b. If eligible for the formulator's exemption, the data requirements listed in Table C.

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[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the formulator's exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end use producers lose the exemption, and become subject to those data requirements.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the registration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and § 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

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[4] Registrations granted after issuance of this Standard will be conditioned upon submission or citation of the data listed in this Registration Standard.

If you are not now eligible for a formulator's exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Formulator's Exemption Statement form.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submission or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submission.

The Agency will also require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number from the Registration Support and Emergency Response Branch, Registration Division. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submissions by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

1. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Development of Data" (EPA Form 8580-6, enclosed).

2. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec. 3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data requirement applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the timeframes for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Testing Protocols, Standards for Conducting Acceptable Tests, Guidance on Evaluating and Reporting Data.

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing.

As noted herein, these EPA Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

F. Procedures for requesting a change in testing protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submission of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols.

G. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time. Any request for a time extension which is made as an initial response to a section 3(c)(2)(B) request notice must be submitted in writing to the Product Manager listed at the end of this section and must be made by the 90-day deadline for response. Once dates have been committed to and EPA has accepted these commitments, any subsequent requests for a time extension must be submitted in writing to the Office of Compliance Monitoring at the address given in Section IX.E.

EPA will view failure to request an extension before the data submission response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome.

A request for an extension does not extend the timeframe for submission of the data. If EPA denies your request for a time extension and you do not submit the data as requested, EPA may begin proceedings to suspend the registrations of your products.

H. PR Notice 86-5 and Any Other Requirements Referenced or Included Within this Notice.

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986).

I. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D, E, F, and G. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6.(cancellation of registration).

Failure to comply with the product-specific data requirements for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMISSION OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 162.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling requirements specific to products containing this pesticide are specified in Section IV.D of this Registration Standard. Applications submitted in response to this notice must include draft labeling for Agency review.

If you fail to submit revised labeling as required, which complies with 40 CFR 162.10 and the specific instructions in Section IV.D., EPA may seek to cancel or suspend the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMISSION

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division for each product subject to this Registration Standard:

a. The "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.[5]

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

d. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

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[5] If on the Summary Sheet, you commit to develop the data, present arguments that a data requirement is not applicable or should be waived, or submit protocols or modified protocols for Agency review, you must submit a copy of the Summary Sheet (and any supporting information) to the Office of Compliance Monitoring, which will be monitoring the data generated in response to this notice. This submission is in addition to responding to the Product Manager, and should be submitted to the Office of Compliance Monitoring at the address given at the end of this section. (Actual studies are not to be submitted to the Office of Compliance Monitoring.)

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Two copies of any required product-specific data (See Table B).

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft label must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

d. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within the time frames set forth in Table A, you must submit to the Registration Division all generic data, unless you are eligible for the formulator's exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Product Manager and the Office of Compliance Monitoring of the problem, the reasons for the problem, and your proposed course of action.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit to the Product Manager in the Registration Division:

a. FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments[5] (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Formulator's Exemption Statement (EPA Form 8570-27), if applicable.

2. Within 9 months from receipt of this document you must submit to the Product Manager:

a. Two copies of any product-specific data, if required by Table C.

b. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

c. Three copies of draft labeling, including the container label and any associated supplemental labeling. Labeling should be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. The draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text. End use product labeling must comply specifically with the instructions in Section IV (Regulatory Position and Rationale).

D. Intrastate Products containing the subject pesticide either as sole active ingredient or in combination with other active ingredients.

These products are being called in for full Federal registration. Producers of these products are being sent a letter instructing them how to submit an application for registration.

E. Addresses

The required information must be submitted to the following address:

Lois Rossi (PM 21)
Registration Division (TS-767C)
Office of Pesticide Programs
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

The address for submissions to the Office of Compliance Monitoring is:

Laboratory Data Integrity Program
Office of Compliance Monitoring (EN-342)
Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460.

APPENDIX I

DATA TABLES

TGUIDE-1

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food
F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

> YES - EPA has data in its files that satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.
>
> PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species, or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.
>
> NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column 3 indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column 5 requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

TABLE A. GENERIC DATA REQUIREMENTS FOR THE TECHNICAL GRADE OF FENAMIPHOS

Data Requirement	Composition[1]	Does EPA Have Data to Satisfy This Requirement?[2]	Bibliographic Citation[2]	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Time Frame For Data Submission
158.120 Product Chemistry					
Product Identity and Composition					
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	No	N/A	Yes[3]	6 months
61-3 - Discussion of Formation of Impurities	TGAI	No	N/A	Yes[4]	6 months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis of Product Samples	TGAI	No	N/A	Yes[5]	12 months
Physical and Chemical Characteristics					
63-2 - Color	TGAI	No	N/A	Yes[6]	6 months
63-3 - Physical State	TGAI	No	N/A	Yes[6]	6 months
63-4 - Odor	TGAI	No	N/A	Yes[6]	6 months
63-5 - Melting Point	TGAI	No	N/A	Yes[6][7]	6 months
63-6 - Boiling Point	TGAI	No	N/A	Yes[6][8]	6 months
63-7 - Density, Bulk Density, or Specific Gravity	TGAI	No	N/A	Yes[6]	6 months

(continued, footnotes follow.)

TABLE A. GENERIC DATA REQUIREMENTS FOR THE TECHNICAL GRADE OF FENAMIPHOS

Data Requirement	Composition[1]	Does EPA Have Data to Satisfy This Requirement?[2]	Bibliographic Citation[2]	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Time Frame For Data Submission
158.120 Product Chemistry (continued)					
63-8 - Solubility	TGAI or PAI	No	N/A	Yes[6]	6 months
63-9 - Vapor Pressure	TGAI or PAI	No	N/A	Yes[6]	6 months
63-10 - Dissociation Constant	TGAI or PAI	No	N/A	Yes[6]	6 months
63-11 - Octanol/Water Partition Coefficient	PAI	No	N/A	Yes[6][9]	6 months
63-12 - pH	TGAI	No	N/A	Yes[6][10]	6 months
63-13 - Stability	TGAI	No	N/A	Yes[6]	6 months
Other Requirements:					
64-1 - Submittal of samples	N/A	N/A	N/A	No	

---

[1] Composition: TGAI = technical grade of the active ingredient; PAI = pure active ingredient.

[2] Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determined that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

TABLE A GENERIC DATA REQUIREMENTS FOR THE TECHNICAL GRADE OF FENAMIPHOS

3/ Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material used to manufacture each product.

4/ A detailed discussion of all impurities that are or may be present at $\geq$0.1%, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

5/ Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used.

6/ Physicochemical characteristics (color, physical state, odor, melting point, boiling point, specific gravity, solubility, vapor pressure, dissociation constant, K_{ow}, pH, and stability) as required in 40 CFR 158.120 and more fully described in the Pesticide Assessment Guidelines, Subdivision D must be submitted.

7/ Data needed if the technical chemical is a solid at room temperature.

8/ Data needed if the technical chemical is a liquid at room temperature.

9/ Required if the technical chemical is organic and non-polar.

10/ Required if the test substance is dispersible with water.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMIPHOS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission
§158.125 Residue Chemistry						
171-2 - Chemical Identity	TGAI		Yes	1/		
171-3 - Directions for Use	—		(See Index)			
171-4 - Nature of Residue (Metabolism)						
- Plants	PAIRA		Yes	00036831 00036837 00038506 00041025 00041027 00041028 00041030 00045595 00045612 00052504 00052509 00052510 00094349 00117405 00119223 00134943	No	
- Livestock	PAIRA & Plant Metabolites		Partially	00035114 00036830 00041206 00134943	Yes 2/3/ Reserved 4/	18 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMIPHOS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission
§158.125 Residue Chemistry						
171-4 - Residue Analytical Method						
- Plant and animal residues	TGAI & Metabolites		Partially	00025103 00025115 00052495 00052526 00105945 00112903 00112904 00118794 00119223 00121865 00128729	Yes[5/]	15 months
171-4 - Storage stability data	PAI and metabolites		Partially	00036839 00045605 00052494 00056049 00112903 00117753 00118794 00119223 00152195	Yes[6/7/8/]	18 months

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMIPHOS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission
§158.125 Residue Chemistry						
171-4 - Magnitude of the Residue-Residue Studies for Each Food Use						
- Crop Group #1 - Bulb Vegetables Group 9/						
• Crop 1 Garlic	TEP		Partially	00103094 00153468	Yes 10/	6 Months
- Crop Group #2 - Brassica Leafy Vegetables Group 11/						
• Crop 1 Brussels sprouts	TEP		Yes	00036826 00036829 00038522 00052508 00118790	No	
• Crop 2 Cabbage	TEP		Yes	00036827 00118790 00119223 00152195 00154528	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMIPHOS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission
§158.125 Residue Chemistry						
-171-4 Magnitude of the Residue						
- Crop Group #3 - Legume Vegetables Group[12]						
• Crop 1 Soybeans — Processed Food/Feed	EP		Partially	00038507 00038508 00109257 00154503 00154528	Yes[13]	24 months
- Crop Group #4 - Citrus Fruits Group[14]						
• Crop 1 Grapefruit			Yes	00038510 00038511 00056049 00101570	No	
• Crop 2 Lemons			Yes	00038509 00038510 00049668 00056049 00101570	No	
• Crop 3 Limes			Yes	00038510 00038511	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMIPHOS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission
§158.125 Residue Chemistry						
-171-4 Magnitude of the Residue						
- Crop Group #4 - Citrus Fruits Group continued						
— Crop 4 Oranges			Yes	00036841 00036842 00038510 00038511 00049668 00056049 00098611 00117406 00134808 00154528	No	
— Crop 5 Tangerines			Yes	00038504	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMIPHOS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission
§158.125 Residue Chemistry						
-171-4. Magnitude of the Residue						
- Group #5 Pome Fruits 15/						
• Crop 1 Apples			Yes	00029106 00112904 00118794	No	
- Group #6 Stone Fruits 16/						
• Crop 1 Cherries			Yes	00029106 00112903 00112904 00118794	No	
• Crop 2 Peaches			Yes	00029106 00112904 00118794	No	
- Group #7 Small Fruits and Berries 17/						
• Crop 1 Grapes — Processed Food/Feed	EP		Partially	00028849 00076988 00098611 00105945 00154528	Yes 18/	24 months
Crop 2 Raspberries	EP		Yes	00087556	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMIPHOS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission
§158.125 Residue Chemistry						
-171-4. Magnitude of the Residue - Crop Field Trials						
-Miscellaneous Commodities						
• Asparagus			Yes	00128729	No	
• Bananas			Partially	00025103 00025112 00025114 00075270	Yes[19]	6 months
• Cocoa beans			Partially	00165546	Yes	24 months[20]
— Processing Study	EP					6 months[21]
	TEP					18 months[22]
• Cottonseed	EP		Partially	00052511 00052518 00055868 00117754 00118790 00154528	Yes	24 months[23] 6 months[24]

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMIPHOS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Time Frame for Submission
§158.125 Residue Chemistry						
-Miscellaneous Commodities						
° Okra			Yes	00106037	No	
° Peanuts — Processed Food/Feed	EP		Partially	00052501 00052525 00078888	Yes[25]	24 months
° Pineapple — Processed Food/Feed	EP		Partially	00079585 00117406 00121866 00134943 00157805	Yes[26/]	24 months
° Tobacco	PAIRA		Partially	40211201 40220001	Yes[27/]	18 months
Nonbearing Orchard Crops	EP		No		Yes[28/] [29/]	18 months
Meat/Milk/Poultry/ Eggs - Feeding studies			Partially	00118794 00119223	Reserved[30/]	
Meat/Milk - Processing Studies	EP		No		Yes[31/]	24 months

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMIPHOS

§158.125 Residue Chemistry - Continued

FOOTNOTES

1/ Refer to Product Chemistry Data Requirement tables.

2/ Metabolism studies using ruminants and poultry are required. Animals must be dosed with ring-labeled [^{14}C] fenamiphos for 3 days at a level sufficient to make residue identification and quantification possible. Milk and eggs must be collected twice daily during the dosing period. Animals must be sacrificed within 24 hours of the final dose. The distribution and identity of residues must be determined in milk, eggs, liver, kidney, muscle, and fat.

3/ Samples from the studies requested above must also be analyzed using current enforcement methods to ascertain the validity of these methods.

4/ Should the metabolism of fenamiphos in ruminants or poultry be found to differ significantly from that in rats, additional swine metabolism studies will be required.

5/ Residues of fenamiphos sulfoxide (FSO) and fenamiphos sulfone (FSO_2) in or on plant and animal commodities and of des-isopropyl fenamiphos, des-isopropyl fenamiphos sulfoxide and des-isopropyl fenamiphos sulfone in animal commodities must be subjected to analysis by the multi-residue protocols. Protocols for methods I, II III, and IV are available from National Technical Information Service under Order No. PB 203734/AS.

6/ Storage stability data providing definition of storage conditions and intervals under which the combined residues of fenamiphos, FSO, and FSO_2 will remain stable in muscle, fat liver, kidney, milk, and eggs.

7/ The storage intervals and conditions of storage of samples used to support all established tolerances for residues of fenamiphos must be submitted. If plant commodity samples were frozen for > 3 years, these data must be accompanied by data depicting the percent decline in residues at the time and under the conditions specified. On receipt of these data, the adequacy of the aforementioned tolerances will be reevaluated.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMIPHOS

§158.125 Residue Chemistry - Continued

FOOTNOTES

8/ All residue data requested in this Standard must be accompanied by data regarding storage intervals and conditions of sample storage. These data must be accompanied by fortification recovery data depicting the stability of fenamiphos residues of concern in appropriate sample substances under the conditions and for the time intervals specified.

9/ If the registrant desires a crop group tolerance, use directions must be proposed, and appropriate supporting residue data submitted for the additional representative group member onion (green and bulb).

10/ Information must be provided detailing the mechansims employed to regulate the use of fenamiphos on garlic grown in all countries which export to the U.S. Such information must include an English language translation of all product label(s).

11/ If the registrant desires a crop group tolerance use directions must be proposed, and appropriate supporting residue data submitted for additional representative group members (broccoli and mustard greens).

12/ If the Registrant desires a crop group tolerance, use directions must be proposed and appropriate supporting residue data submitted for the additional representative group members (beans and peas).

13/ Residue data for dust (grain), soybean hulls, meal, crude oil, and refined oil processed from soybeans bearing measurable weather residues are required. Exaggerated rates may be necessary to achieve these residue levels. If residues concentrate in these processed products, appropriate food/feed additive tolerances will have to be proposed.

14/ Based on the available residue data and the use pattern for citrus, a group tolerance of 0.5 ppm for residues in or on citrus fruits appears to be appropriate and will permit compatibility with the Codex MRL.

15/ If the registrant desires a crop group tolerance, use directions must be proposed and appropriate supporting residue data submitted for the additional representative group members (pears).

16/ If the registrant desires a crop group tolerance, use directions must be proposed and appropriate supporting residue data submitted for the additional representative group member (plums, fresh prunes).

17/ If the registrant desires a crop group tolerance, use directions must be proposed and appropriate supporting residue data submitted for additional representative group members (cranberry, blueberry, and strawberry).

18/ Data depicting fenamiphos residues of concern in juice and dehydrated grape pomace processed from grapes bearing measurable, weathered residues are required. Upon receipt of the requested data, the established tolerance for residues in grape pomace may have to be revised. Also, if the data indicate a potential for concentration in juice, an appropriate food additive tolerance must be proposed.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMIPHOS

§158.125 Residue Chemistry - Continued

FOOTNOTES

19/ Approved labels (use directions) from all countries in which the product is marketed must be submitted. Information must be provided detailing the mechanisms employed to regulate the use of fenamiphos on bananas for the U.S. market. Such information must include an English language translation of the product label(s).

20/ Data depicting the potential for concentration of residues in roasted beans, cocoa powder, and chocolate processed from cocoa beans bearing measurable, weathered residues are required. If the data indicate a potential for residue concentration in any of these commodities, appropriate food additive tolerances must be proposed.

21/ Information must be provided detailing the mechanisms employed to regulate the use of fenamiphos on cocoa trees grown in all countries from which cocoa beans are imported into the U.S. Such information must include English language translation of the product label(s).

22/ Residue data must be submitted in which crops were treated at maximum permitted label rates and harvested within 1 day of treatment and at regular intervals thereafter. Tests must be conducted in representative countries in which use is permitted and the crop is exported to the U.S.

23/ Data depicting residues of concern from meal, hulls, soapstock, crude oil, and refined oil processed from cottonseed bearing measurable weathered residues. Exaggerated rates may be necessary to achieve these residue levels.

24/ The registrant(s) must propose a tolerance of 0.1 ppm for residues of fenamiphos in or on cotton forage. Alternatively, the registrant(s) may amend the use directions to include feeding restrictions for cotton forage.

25/ Data depicting combined residues of fenamiphos and its sulfoxide and sulfone metabolites in meal, crude oil, refined oil, and soapstock derived from nuts bearing measurable weathered residues. If concentration of residues occurs during processing, the registrant must propose appropriate food/feed additive tolerances.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMIPHOS

§158.125 Residue Chemistry - Continued

FOOTNOTES

26/ Data from a processing study depicting the combined residues of fenamiphos and its sulfoxide and sulfone metabolites in pineapple juice and dried pineapple bran processed from whole pineapple fruit (excluding crown) bearing measurable weathered residues. If the requested data indicate a concentration of residues in pineapple juice and/or a concentration factor in dried pineapple bran greater than 33, then appropriate food and/or feed additive tolerances must be proposed.

27/ Pyrolysis products derived from the active ingredient must be characterized and the level of residue in tobacco smoke must be quantified. (Weathered residues of [^{14}C] fenamiphos must be used for identification of pyrolysis products).

28/ Residue data for tree nuts grown from nursery stock which had been treated with single applications of the 15% G or 3 lb/gal EC formulation at 18 lb ai/A are required. The tests must be conducted in California. Alternatively, the registrant may elect to cancel this use permitted under Section 24(c) Special Local Need registrations.

29/ Residue data for pears grown from nursery stock which had been treated with the 15% G or 3 lb/gal EC formulation at 20 lb ai/A are required. The tests must be performed in Oregon. Alternatively, the registrant may elect to cancel this use permitted under Section 24(c) Special Local Need registrations.

30/ We note that the nature of the residue in animals is not adequately understood and outstanding data gaps exist for many processed feed items. Upon receipt of the data requested in the sections "Nature of the Residue in Animals" and "Magnitude of the Residue in Animals", the established tolerances will be assessed, and the adequacy of the available data regarding the magnitude of residues will be determined with consideration for any additional metabolites of toxicological concern.

31/ Processing studies are required that demonstrate the effect of cooking (meat) and pasteurization or production of infant formula (milk) on residue levels of fenamiphos and its sulfoxide and sulfone as well as des-isopropyl fenamiphos, des-isopropyl fenamiphos sulfoxide, and des-isopropryl fenamiphos sulfone. A protocol should be submitted for Agency approval prior to initiation of the study.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMIPHOS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.130 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 - Hydrolysis	TGAI or PAIRA	A,B	Yes	00079270	No	
Photodegradation						
161-2 - In water	TGAI or PAIRA	A,B	Yes	00133402	No	
161-3 - On soil	TGAI or PAIRA	A	No		Yes	9 Months
161-4 - In Air	TGAI or PAIRA		No		No[1]	
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	A,B	No		Yes	27 Months
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No		Yes	27 Months
162-3 - Anaerobic Aquatic	TGAI or PAIRA		No		No[1]	
162-4 - Aerobic Aquatic	TGAI or PAIRA		No		No[1]	
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/Desorption	TGAI or PAIRA	A,B	No		Yes	12 Months
163-2 - Volatility (Lab)	TEP	A	No		Yes	12 Months
163-3 - Volatility (Field)	TEP	A	No		Reserved[2]	15 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMIPHOS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.130 Environmental Fate - Continued						
DISSIPATION STUDIES–FIELD:						
164-1 - Soil	TEP	A,B	No		Yes	27 Months
164-2 - Aquatic (Sediment)	TEP		No		No[1]	
164-3 - Forestry	TEP		No		No[1]	
164-4 - Combination and Tank Mixes	TEP		No		No[3]	—
164-5 - Soil, Long-term	TEP	A	No		Reserved[4]	50 Months
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	A	No		Yes	39 Months
165-2 - Rotational Crops (Field)	TEP	A	No		Yes	50 Months
165-3 - Irrigated Crops	TEP		No		Yes	39 Months
165-4 - In Fish	TGAI or PAIRA	A,B	No		Yes	12 Months
165-5 - In Aquatic Non-Target Organisms	TEP		No		No[1]	
158.142 Spray Drift						
201-1 Droplet Size Spectrum	TEP	A,B	No		Yes[5]	6 Months
202-1 Drift Field Evaluation	TEP	A,B	No		Yes[5]	6 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMIPHOS

§158.130 Environmental Fate - Continued

1/ Not required based on the use pattern of fenamiphos.

2/ Reserved pending results of the laboratory volatility study.

3/ Tank mix data requirements are not being imposed by this standard.

4/ Soil long term study is reserved pending the results of aerobic soil metabolism and field dissipation studies.

5/ The spray drift droplet spectrum and field evaluation may be done together in order to evaluate the droplet spectrums that are associated with actual field use patterns.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMIPHOS

Date Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted	Time Frame for Submission
§158.135 Toxicology						
ACUTE TESTING:						
81-1 - Acute Oral Toxicity - Rat	TGAI	A,B,G	Yes	00033831	No	
81-2 - Acute Dermal Toxicity - Rabbit	TGAI	A,B,G	Yes	00037962	No	
81-3 - Acute Inhalation - Rat	TGAI	A,B,G	Yes	00154492	No	
81-4 - Eye Irritation - Rabbit	TGAI	A,B,G	Yes	00082111	No	
81-5 - Dermal Irritation - Rabbit	TGAI	A,B,G	Yes	00082111	No	
81-6 - Dermal Sensitization - Guinea Pig	TGAI	A,B,G	Yes	00148464	No	
81-7 - Delayed Neurotoxicity - Hen	TGAI	A,B,G	Yes	00057606	No	
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding: - Rodent, and	TGAI	A	Yes	00117403 00119240 00133475	No	
- Non-rodent (Dog)	TGAI	A	Yes	00117403 00154493	No	
82-2 - 21-Day Dermal - Rabbit	TGAI	A,B,G	Yes	00154497	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMIPHOS

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicology - Continued						
SUBCHRONIC TESTING CONT'D:						
82-3 - 90-Day Dermal - Rabbit	TGAI	—	No	—	No[1]	
82-4 - 21-Day Inhalation: - Rat	TGAI	—	No	—	Yes[2]	12 Months
82-5 - 90-Day Neurotoxicity:	TGAI	—	No	—	No[3]	
CHRONIC TESTING:						
83-1 - Chronic Toxicity - 2 species:						
- Rodent, and	TGAI	A	Yes	00161361 00133475	No	
- Non-rodent (Dog)	TGAI	A	Yes	00037965 00154493	No	
83-2 - Oncogenicity - 2 species:						
- Rat (preferred), and	TGAI	A	Yes	00161361	No	
- Mouse (preferred)	TGAI	A	Yes	00098614	No	
83-3 - Teratogenicity - 2 species:						
- Rat	TGAI	A	No	—	Yes	15 Months
- Rabbit	TGAI	A	No	00121286	Yes	15 Months
83-4 - Reproduction - Rat 2-generation	TGAI	A	Yes	00037979	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMIPHOS

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicology - Continued						
MUTAGENICITY TESTING						
84-2 - Gene Mutation (Ames Test)	TGAI	A,B,G	Yes	00159027	No	
84-2 - Structural Chromosomal Aberration	TGAI	A,B,G	Yes	00086981	No	
84-4 - Other Genotoxic Effects	TGAI	A,B,G	No		Yes[4]	12 Month
SPECIAL TESTING						
85-1 - General Metabolism	PAI or PAIRA	A	Partially	00041022 00041023 00052527 00033831	Yes[5]	24 Mon
85-2 - Antidotal	TGAI	A,B,G	Yes	00082807	No	

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMIPHOS

§158.135 Toxicology - Continued

1/ The registered uses do not require a 90-day dermal study.

2/ A test with duration of 21 days is required if product is used on tobacco.

3/ Fenamiphos was negative for neurotoxicity in the acute delayed neurotoxicity study (81-7) and is without evidence of neurotoxicity in other mammalian test species.

4/ Additional testing is required to assess direct DNA damage.

5/ A Guideline multiple-dose rat metabolism study is required.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMIPHOS

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.140 Reentry Protection						
132-1 - Foliar Dissipation	TEP	A,B	No		Yes[1]	27 Months
132-1 - Soil Dissipation	TEP	A,B	No		Yes[2]	27 Months
133-3 - Dermal Exposure	TEP		No		Yes[3]	27 Months
133-4 - Inhalation Exposure	TEP		No		Yes[3]	27 Months

1/ For each end-use, the Registrant is required to propose an acceptable reentry interval based either upon; data on dissipation of residues (decline curve), human exposure to those residues, and toxicity of the residues; or upon a determination of that time beyond which there are no detectable dislodgeable or inhalable residues remaining in the worker/occupant environment. If the Registrant has reason to believe that an end-use will not cause exposure to residues, a request for waiver from this data requirement should be submitted.

2/ Soil dissipation data are required only for uses where workers will be exposed directly to substantial quantities of soil during their work, e.g. for use on cotton where hand harvesting will be performed.

3/ Human exposure monitoring data must be submitted if the Registrant wishes to use the "allowable exposure method" of determining reentry intervals. If exposure studies are submitted, both dermal exposure and inhalation exposure must be submitted. If exposure studies are not submitted, human exposure (and reentry intervals) would be estimated from dislodgeable residues as explained in Subdivision K.

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMIPHOS

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
71-1 - Acute Avian Oral Toxicity	TGAI	A,B	Yes	00121289	No	
71-2 - Avian Subacute Dietary Toxicity						
- Upland Game Bird, and	TGAI	A,B	Yes	00025959	No	
- Waterfowl	TGAI	A,B	Yes	00025958	No	
71-3 - Wild Mammal Toxicity	TGAI	A,B	N/A		No[1]	
71-4 - Avian Reproduction						
- Upland Game Bird, and	TGAI	A,B	Yes	00121291	No	
- Waterfowl	TGAI	A,B	Yes	00121290	No	
71-5 - Simulated Field Testing						
- Mammals, and	TEP	A,B	No		Yes[2]	48 months
- Birds	TEP	A,B	No		Yes[2]	48 months
- Actual Field Testing						
- Mammals, and	TEP	A,B	No		Yes[2]	48 Months
- Birds	TEP	A,B	No		Yes[2]	48 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMIPHOS

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms - Continued						
AQUATIC ORGANISM TESTING						
72-1 - Freshwater Fish Toxicity - Coldwater Fish Species, and	TGAI	A,B	Yes	00114012	No	
- Warmwater Fish Species	TGAI	A,B	Yes	00025962	No	
- Coldwater Fish Species	TEP (21 & 35% EC)	A,B	Partial	00114012	Yes 3/	9 Months
- Warmwater Fish Species	TEP (21 & 35% EC)	A,B	Partial	00114012	Yes 3/	9 Months
- Warmwater Fish Species	Sulfoxide degradate	A,B	Yes	00025962 00114015	No	
	Sulfone degradate	A,B	Yes	00025962	No	
72-2 - Acute Toxicity to Freshwater Invertebrates	TGAI	A,B	No	00025960	Yes	9 Months
	TEP (21 & 35%)	A,B			Yes 4/	9 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMIPHOS

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms - Continued						
AQUATIC ORGANISM TESTING						
72-3 - Acute Toxicity to Estuarine and Marine Organisms						
- Fish	TGAI	A,B	No	00094220	Yes 5/	12 Months
- Mollusk	TGAI	A,B	No	00094220	Yes 5/	12 Months
- Shrimp	TGAI	A,B	No	00094220	Yes 5/	12 Months
72-4 - Fish Early Life Stage, and	TGAI	A,B	No		Yes 6/	15 Months
- Aquatic Invertebrate Life-Cycle	TGAI	A,B	No		Yes	15 Months
72-5 - Fish - Life-Cycle	TEP	A,B	No		Yes	27 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMIPHOS

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.145 Wildlife and Aquatic Organisms - Continued						
72-6 - Aquatic Organism Accumulation	TEP	A,B	No		Yes	
- Crustacean						12 Months
- Fish						12 Months
- Insect Nymph						12 Months
- Mollusk						12 Months
72-7 - Simulated Field Testing - Aquatic Organisms	TEP	A,B	No		Yes[7]	48 Months
- Actual Field Testing -Aquatic Organisms	TEP	A,B	No		Yes[7]	48 Months

TABLE A
GENERIC DATA REQUIREMENTS FOR FENAMIPHOS

§158.145 Wildlife and Aquatic Organisms - Continued

1/ The Agency will use acute toxicology data to satisfy this requirement.

2/ Actual field testing with birds and mammals is required as per 40 CFR 158.145 with a typical granular formulation. Initial sites to be tested, based on application rates and wildlife usage information, include tobacco, citrus, sod and turf (broadcast applications). The application rates to be used are the lowest rates that are still efficacious as indicated by the required efficacy data (Appendix I, Table B, § 158.160). Initial testing must include a study of dietary exposure and thorough carcass searching to determine whether there is pesticide induced mortality, and if so, its extent. Examination of the citrus use must also determine, by nest survey, whether avian breeding is disrupted, and collect complete natality, mortality, emigration, and immigration data. It must be determined, by mark-recapture techniques, whether mammalian populations are also affected. Also required is a field study of band application of the 15G formulation in fruit trees at 20 lb ai/A, with carcass searching as above. Multiple sites are required for all use patterns studied. Additional field testing is reserved pending results of these studies and additional environmental fate testings. Cancellation of any of the above use patterns would obviate the need for testing of these uses. However, since further studies are pending the results of the above initial testing, other sites may be required to be substituted. The Agency requires protocols for conducting the studies be submitted for review within 6 months of the issuance of the standard and accepted by the Agency prior to initiation of field work. The study is due 48 months from publication of this Registration Standard but annual progress reports must be submitted for the duration of the study. A guidance document is available from the Agency which outlines an acceptable approach to these studies and the Agency encourages registrants to consult with Agency staff for assistance if required.

3/ Accepted studies were conducted on the 15G, but additional studies must be conducted on the 35 and 21% spray concentrate products. Estimated EECs from recommended application rates exceed the LC_{50} values.

4/ Product is highly toxic fungicide and Estimated Environmental Concentrations (EECs) are likely to exceed 48-hour LC_5 for the technical material.

5/ To support citrus, cotton, and peanut uses (crops exceeding 300,000 acres in coastal counties) and tobacco of which 56% is treated with fenamiphos.

6/ Test required because LC_{50} values for warm- and coldwater fish species were less than 1 mg/L LC_{50} values.

7/ The Agency requires protocols for conducting the studies be submitted for review within 6 months of the issuance of the standard and accepted by the Agency prior to initiation of field work. The study is due 48 months from publication of this Registration Standard but annual progress reports must be submitted for the duration of the study. A guidance document is available from the Agency which outlines an acceptable approach to these studies and the Agency encourages registrants to consult with Agency staff for assistance, if required. The application rates to be used are the lowest rates that are still efficacious as indicated by the required efficacy data (Appendix I, Table B §158.160).

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING USE PRODUCTS CONTAINING FENAMIPHOS

Data Requirement	Composition 1/	Does EPA Have Data to Satisfy This Requirement? 2/	Bibliographic Citation 2/	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Time Frame For Data Submission
158.120 Product Chemistry					
Product Identity and Composition					
61-1 - Product Identity and Disclosure of Ingredients	MP	No	N/A	Yes 3/	6 months
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No	N/A	Yes 4/	6 months
61-3 - Discussion of Formation of Impurities	MP	No	N/A	Yes 5/	6 months
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis of Product Samples	MP	No	N/A	Yes 6/	12 months
62-2 - Certification of Ingredient Limits	MP	No	N/A	Yes 7/	12 months
62-3 - Analytical Methods to Verify Certified Limits	MP	No	N/A	Yes 8/	12 months

(continued, footnotes follow.)

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING USE PRODUCTS CONTAINING FENAMIPHOS

Data Requirement	Composition[1]	Does EPA Have Data to Satisfy This Requirement?[2]	Bibliographic Citation[2]	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Time Frame For Data Submission
158.120 Product Chemistry (continued) Physical and Chemical Characteristics					
63-2 - Color	MP	No	N/A	Yes[9]	6 months
63-3 - Physical State	MP	No	N/A	Yes[9]	6 months
63-4 - Odor	MP	No	N/A	Yes[9]	6 months
63-7 - Density, Bulk Density, or Specific Gravity	MP	No	N/A	Yes[9]	6 months
63-12 - pH	MP	No	N/A	Yes[9][10]	6 months
63-14 - Oxidizing or Reducing Action	MP	No	N/A	Yes[9][11]	6 months
63-15 - Flammability	MP	No	N/A	Yes[9][12]	6 months
63-16 - Explodability	MP	No	N/A	Yes[9][13]	6 months
63-17 - Storage Stability	MP	No	N/A	Yes[9]	15 months
63-18 - Viscosity	MP	No	N/A	Yes[9][14]	6 months
63-19 - Miscibility	MP	No	N/A	Yes[9][15]	6 months
63-20 - Corrosion Characteristics	MP	No	N/A	Yes[9]	15 months
Other Requirements:					
64-1 - Submittal of samples	N/A	N/A	N/A	No	

(continued, footnotes follow).

TABLE B PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING USE PRODUCTS CONTAINING FENAMIPHOS

1/ Composition: MP = Manufacturing Use Product.

2/ Not applicable. Although product chemistry data may have been submitted in the past, the Agency has determine that these data must be resubmitted for each pesticide. New requirements have been introduced and previously submitted data must be updated. Therefore, bibliographic citations for the old data are not applicable.

3/ The chemical name and nominal concentration of each impurity for which a certified limit is required must be submitted. In addition, the chemical name, nominal concentration, Chemical Abstracts (CAS) Registry Number, an purpose of the active ingredient and each intentionally added inert must be provided. For the active ingredien the following must also be provided: the product name, trade name, and common name; the molecular, structural, and empirical formulas; the molecular weight or weight range; and any experimental or internally assigned compa code numbers.

4/ Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material must be provided, along with information regarding the properties of each beginning material used to manufacture each product.

5/ A detailed discussion of all impurities that are or may be present at $\geq 0.1\%$, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production must be submitted.

6/ Five or more representative samples must be analyzed for the amount of active ingredient and each impurity for which a certified limit is required. Complete validation data (accuracy, precision) must be submitted for each analytical method used.

TABLE B. PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING USE PRODUCTS CONTAINING FENAMIPHOS

7/ Upper and lower limits for the active ingredient and each intentionally added inert, and upper limits for each impurity present at ≥0.1% (w/w) and each "toxicologically significant" impurity present at <0.1% (w/w) must be provided, certified, and validated by sample analysis using analytical procedures for which accuracy and precision data have been provided. Limits for impurities not associated with the active ingredient need be provided only if they are considered to be of toxicological significance, regardless of the concentration at which they are present. [We defer to the Toxicology Branch regarding the toxicological significance of (i) impurities associated with the active ingredient present at <0.1% (w/w) and (ii) impurities not associated with the active ingredient.] Certifications must be submitted on EPA Form 8570 Rev. 2-85.

8/ Analytical methods must be provided to determine the active ingredient, and each toxicologically significant impurity and intentionally added inert for which certified limits are required. Each method must be accompanie by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits. [RCB defers to the TOX Branch regarding the toxicological significance of impurities and intentionally added inerts for which certified limits are required.]

9/ Physicochemical characteristics (color, physical state, odor, specific gravity, pH, oxidizing or reducing action, flammability, exploidability, storage stability, viscosity, miscibility, and corrosion characteristics) as required in 40 CFR 158.120 and more fully described in the Pesticide Assessment Guidelines, Subdivision D must be submitted.

10/ Required if the test substance is dispersible with water.

11/ Required if the product contains an oxidizing or reducing agent.

12/ Required if the product contains combustible liquids.

13/ Required if the product is potentially explosive.

14/ Required if the product is a liquid.

15/ Required if the product is a liquid and is to be diluted with petroleum solvents.

TABLE B

PRODUCT SPECIFIC DATA REQUIREMENTS FOR MANUFACTURING-USE PRODUCTS CONTAINING FENAMIPHOS

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.135 Toxicology						
ACUTE TESTING						
81-1 - Acute Oral Toxicity - Rat	MP	A,B,G	Yes	0033831	No	
81-2 - Acute Dermal Toxicity - Rabbit	MP	A,B,G	No	0037962	No	
81-3 - Acute Inhalation Toxicity - Rat	MP	A,B,G	No	0154492	No	
81-4 - Primary Eye Irritation - Rabbit	MP	A,B,G	No	00082111	No	
81-5 - Primary Dermal Irritation - Rabbit	MP	A,B,G	No	00082111	No	
81-6 - Dermal Sensitization - Guinea Pig	MP	A,B,G	No	00148464	No	

TABLE C
PRODUCT SPECIFIC DATA REQUIREMENTS FOR END-USE PRODUCTS CONTAINING FENAMIPHOS

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data?	Bibliographic Citation	Must Additional Data be Submitted?	Time Frame for Submission
§158.160 Product Performance						
96-10 - Nematicides	TEP	A,B,G	No		Yes	6 Months

APPENDIX II

LABELING

SUMMARY-1

LABEL CONTENTS

40 CFR 162.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label text. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 162.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 162.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 162.10(f)]

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 162.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely. [40 CFR 162.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement. [40 CFR 162.10 (h)(1)(i)]

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON. [40 CFR 162.10(h)(1)(i)]

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 162.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "See Side (or back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 162.10(h)(1)(iii)]

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 162.10(h)(2)].

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 162.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 162.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 162.10(h)(1)(iv)

b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 162.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-6

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by. . .," etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

SUMMARY-7

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all.	
7E	Referral statement	All products where precautionary labeling appears on other than front panel.	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under the headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

PHYSICAL/CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. All Other Pressurized Containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. Keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STOR-1

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.

2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.

3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.

4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.

5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.

6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONT/DIS-1

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording)

1/ Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

APPENDIX III

USE INDEX

EPA Index to Pesticide Chemicals

ETHYL 3-METHYL-4-(METHYLTHIO)PHENYL 1-(METHYLETHYL) PHOSPHORAMIDATE (9CA)

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:100601

ETHYL 3-METHYL-4-(METHYLTHIO)PHENYL 1-(METHYLETHYL) PHOSPHORAMIDATE (9CA)*

TYPE PESTICIDE: Nematicide, Insecticide

FORMULATIONS:

Tech	(85%)
FI	(72.3%)
G	(5%, 10%, 15%)
EC	(2 lb/gal, 3 lb/gal)

GENERAL WARNINGS AND LIMITATIONS: The 2 and 3 pound per gallon emulsifiable concentrate formulations are RESTRICTED USE PESTICIDES. Mixer/loaders must wear protective coveralls, rubber or neoprene boots, rubber or neoprene gloves, and goggles or face shields when handling products containing this chemical. Any person coming in direct contact with treated water, and/or treated soil prior to incorporation or irrigation, must wear protective coveralls, rubber or neoprene boots and rubber or neoprene gloves. Do not graze treated areas or feed cover crops grown in treated areas to livestock.

Dosage rates are given in active ingredient.

Agricultural Tolerances (other than those listed in the text):

Asparagus	0.02 ppm
Bananas	0.1 ppm
Cocoa beans	0.02 ppm
Garlic	0.5 ppm
Grapefruit	0.6 ppm
Lemons	0.6 ppm
Limes	0.6 ppm
Oranges	0.6 ppm
Tangerines	0.6 ppm

Livestock Tolerances:

Cattle, fat	0.05 ppm
Cattle, meat	0.05 ppm
Cattle, mbyp	0.05 ppm
Goats, fat	0.05 ppm
Goats, meat	0.05 ppm
Goats, mbyp	0.05 ppm
Hogs, fat	0.05 ppm
Hogs, meat	0.05 ppm
Hogs, mbyp	0.05 ppm
Horses, fat	0.05 ppm
Horses, meat	0.05 ppm
Horses, mbyp	0.05 ppm
Milk	0.05 ppm
Sheep, fat	0.05 ppm
Sheep, meat	0.05 ppm
Sheep, mbyp	0.05 ppm

Definition of Terms:

SLN - Special Local Needs

*fenamiphos
Nemacur

ETHYL 3-METHYL-4-(METHYLTHIO)PHENYL 1-(METHYLETHYL) PHOSPHORAMIDATE (9CA)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	TERRESTRIAL FOOD CROP		
	(Agricultural Crops)		
/04001AA /04001DA /05002AA /05002DA /05004AA /05004DA	Apple Cherry Peach		0.25 ppm (apple, cherry, peach) For all areas except CA. Do not apply within 72 days of harvest for apples, or within 45 days of harvest for peaches or cherries. Do not apply more than 20 pounds per year per planting site. Avoid contacting foliage with the spray mixture or with the granular material.
NABAAAA	Nematodes	10-20 lb/A (10%, 15% G) 003125-00237 (3 lb/gal EC) 003125-00283	Soil treatment. Band application: Apply specific dosage (in 20 to 40 gallons of water for the spray) as spray or granules to the soil surface with equipment properly calibrated to apply fenamiphos in a band covering the feeder root system of the tree. Incorporate immediate 2 to 4 inches deep. Broadcast application is accomplished similar to that described above, but is uniformly applied to the entire orchard area to be treated.
/13006AA	Brussels Sprouts (transplanted)		0.1 ppm
NABAAAA	Nematodes	1.65-3.3 oz/ 1,000 ft of row or 4.0-6.0 lb/A (15% G) 003125-00236	Soil treatment. Band application: Apply specific dosage in ounces per 1,000 feet of row in front of the planting shoe as a 12 to 15 inch band. Incorporate the granules into the soil to a depth of 2 to 6 inches. Broadcast application: Distribute the granules uniformly over the entire area to be treated. For both the band and broadcast treatments, use the high rate in fields with high nematode population, or in fields having a history of serious nematode damage.

EPA Index to Pesticide Chemicals

ETHYL 3-METHYL-4-(METHYLTHIO)PHENYL 1-(METHYLETHYL) PHOSPHORAMIDATE (9CA)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/13007AA	Cabbage (direct seeded and transplanted)		0.1 ppm
NABAAAA	Nematodes	1.65-3.3 oz/ 1,000 ft of row or 4.0-6.0 lb/A (15% G) 003125-00236	Soil treatment. Band application: Apply specific dosage in ounces per 1,000 feet of row in front of the planting shoe as a 12 to 15 inch band. Incorporate the granules into the soil to a depth of 2 to 6 inches. Broadcast application: Distribute the granules uniformly over the entire area to be treated. For both the band and broadcast treatments, use the high rate in fields with high nematode population, or in fields having a history of serious nematode damage.
	Cherry		See Apple cluster.
/02000AA	Citrus		0.6 ppm For use in AZ and TX only. Do not apply within 180 days of harvest. Do not apply more than once per season.
NABAAAA	Nematodes	10-20 lb/A (10%, 15% G) 003125-00237 (3 lb/gal EC) 003125-00283	Soil application. Band treatment: Apply specific dosage (in 20 to 40 gallons of water for the spray) as spray or granules to the soil surface with equipment properly calibrated to apply fenamiphos in a band centered on the row and applied outward to the dripline. (Example: To treat trees planted on 20 foot centers with a 10 foot band centered on the row, apply 0.5 the broadcast rate.) Broadcast application is accomplished similar to that described above, but is uniformly applied to the entire area of the orchard. For both the broadcast and the band applications, follow immediately and incorporate 2 to 3 inches into the soil or apply sufficient irrigation water for incorporation (0.5 to 1 inch for dry conditions).

ETHYL 3-METHYL-4-(METHYLTHIO)PHENYL 1-(METHYLETHYL) PHOSPHORAMIDATE (9CA)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/21001AA	Cotton		0.05 ppm (cotton seed)
NABAAAA IMOAAAA	Nematodes Thrips	1.0-2.2 lb/A on 40 in. row spacing or 1.2-2.7 oz/ 1,000 ft of row (10%, 15% G) 003125-00237 (3 lb/gal EC) 003125-00283	Soil application. In furrow/covering soil: Apply specific dosage (as granules or spray) per 1,000 feet of row in furrow or band in covering soil behind the seed drop. Band: Apply specific dosage per 1,000 feet of row (as granules or spray) in a 6 to 12 inch band over the row. Incorporate thoroughly to insure uniform distribution. Use the highest recommended rates in fields with a history of nematode problems.
IMOAAAA	Thrips	0.75-1.0 lb/A on 40 in. row spacing or 0.9-1.2 oz/ 1,000 ft of row (10%, 15% G) 003125-00237 (3 lb/gal EC) 003125-00283	Soil application. In furrow/covering soil: Apply specific dosage (as granules or spray) per 1,000 feet of row in furrow or band in covering soil behind the seed drop and in front of the covering devices.
/01020AA	Grapes		0.1 ppm
NABAAAA	Nematodes	9.0-18.0 lb/A (3 lb/gal EC) 003125-00283	Soil application (for use east of the Rocky Mountains). Broadcast: Apply specific dosage in 20 to 40 gallons of spray solution per acre to the soil with suitable ground equipment and incorporate 2 to 4 inches deep. Band: Use proportionally less fenamiphos per acre. Treated band should center on vine row with a minimum width of 50 percent of the row spacing. Incoporate immediately. (If the band is half the row width, use 0.5 the rate.)
		9.0-18.0 lb/A (3 lb/gal EC)	Soil application (for use west of the Rocky Mountains). Broadcast: With ground injection equipment, apply specific dosage per acre in 20 to 40 gallons of solution 2 or more inches below the soil surface.

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Grapes (continued)		Band: With ground injection equipment, apply specific dosage per acre in 20 to 40 gallons 2 or more inches below the soil surface. Center the treated band on the vine row using a minimum band width equal to 50 percent of the row spacing (with a band width equaling 50 percent of the row spacing, use 0.5 the broadcast rate).
15015AA	Okra		0.3 ppm For all areas except CA. When band applications are made to narrow row crops, do not use band widths that will allow the treated areas to overlap.
WABAAAA	Nematodes	2.1-2.5 lb/A (15% G) 003125-00236	Soil application. Broadcast. Distribute uniformly over the entire area to be treated and immediately incorporate to a depth of 2 to 6 inches by disking or tilling.
		2.2-2.76 oz/A (15% G)	Band. Apply specific dosage in ounces per 1,000 feet of row in front of the planter shoe as a 12 to 15 inch band. Incorporate the granules into the soil to a depth of 2 to 6 inches.
	Peach		See Apple cluster.

ETHYL 3-METHYL-4-(METHYLTHIO)PHENYL 1-(METHYLETHYL) PHOSPHORAMIDATE (9CA)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/06013AA	Pineapple		0.3 ppm
	(for use in HI only)		Do not apply within 30 days before harvest. Do not use green forage and fodder for animal feed. Do not apply more than 40 pounds fenamiphos per acre per plant crop or more than 20 pounds per acre per ratoon crop.
WEOBCAA	Nematodes (Meloidogyne spp.)	0.5-3.0 lb/A (3 lb/gal EC) 003125-00283	Plant crop: Soil or water treatment. Apply specific dosage in 50 to 250 gallons per acre as a broadcast spray or through drip irrigation. Applications may begin immediately after planting. Make additional applications at intervals of 1 to 3 months as needed. Ratoon crop: Soil or water treatment. Apply specific dosage in 50 to 250 gallons per acre as a broadcast spray or through drip irrigation. Application may begin immediately after crop harvest. Make additional applications at intervals of 1 to 3 months as needed.
WEHBBAA	Nematodes (Rotylenchulus spp.)		
	(for use in PR only)		Do not apply within 7-1/2 months before harvest. Do not use green forage and fodder for animal feed. Do not apply more than 20 pounds fenamiphos per acre per season, regardless of the method of application used.
NABAAAA	Nematodes	5-10 lb/A (3 lb/gal EC)	Plant crop: Soil treatment. Apply specific dosage in 50 to 250 gallons per acre as a broadcast spray. Begin application 1 to 3 months after planting. Make additional applications at intervals of 3 to 6 months as needed. (Note: A preplant soil application of fenamiphos 15 percent granular, or a soil fumigant applied according to label directions, should be made in addition to postplant broadcast applications of fenamiphos.) Ratoon crop: Soil treatment. Apply specific dosage in 50 to 250 gallons per acre as a broad-

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Pineapple (continued)		cast spray. Make first applications immediately following crop harvest. Make additional applications at intervals of 3 to 6 months as needed.
/28015AA	Peanuts		0.02 ppm (peanuts) 0.4 ppm (peanut hulls) When band applications are used on narrow row crops, do not use band widths that will allow treated areas to overlap.
ABAAAA	Nematodes	1.65-2.8 oz/ 1,000 ft of row or 1.5-2.55 lb/A on 36 in. row (10%, 15% G) 003125-00237 (3 lb/gal EC) 003125-00283	Preplant soil treatment. Band application. Apply specific dosage in front of the planter shoe as a 12 to 18 inch band. Incorporate the granules into the soil to a depth of 2 to 6 inches. Use the higher rates in fields with high populations of nematodes or in fields having a history of serious nematode damage.
		3.0-5.1 lb/A (10%, 15% G) (3 lb/gal EC)	Preplant soil treatment. Broadcast application. Distribute the granules of spray uniformly over the entire area to be treated and thoroughly incorporate. Use the higher rates in fields with high populations of nematodes or in fields having a history of serious nematode damage. Plant crop in the usual manner.

ETHYL 3-METHYL-4-(METHYLTHIO)PHENYL 1-(METHYLETHYL) PHOSPHORAMIDATE (9CA)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/01006AA	Raspberry		0.1 ppm For all areas except CA. Do not apply within 6 months of harvest. Do not apply more than twice per year.
NABAAAA	Nematodes	6-12 lb/A (3 lb/gal EC) 003125-00283	Soil treatment. Broadcast application. Apply specific dosage per acre as a broadcast spray to established plantings during the period October 1 to December 31 when adequate rainfall can be expected. Apply in sufficient water to insure uniform distribution (15 to 100 gallons of spray mixture per acre). Direct spray to the soil surface and the base of the plant. Use the high rate in fields with high populations of nematodes or in fields having a history of serious nematode damage.
/28023AA	Soybeans (for all areas except CA)		0.05 ppm When band applications are used on narrow row crops, do not use band widths that will allow treated areas to overlap.
NABAAAA	Nematodes	1.19-3.3 oz/ 1,000 ft of row or 1.1-3.0 lb/A on 36 in. row (10%, 15% G) 003125-00237 (3 lb/gal EC) 003125-00283	Preplant soil treatment. Band application. Apply specific dosage in front of the planter shoe as a spray or granular application on a 12 to 18 inch band. Incorporate the product into the soil to a depth of 2 to 6 inches. Use the higher rates in fields with high populations of nematodes or in fields having a history of serious nematode damage.
		4.0-6.0 lb/A (10%, 15% G) (3 lb/gal EC)	Preplant soil treatment. Broadcast application. Distribute the granules or spray uniformly over the entire area to be treated and thoroughly incorporate. Use the higher rates in fields with high populations of nematodes or in fields having a history of serious nematode

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Soybeans (continued)		
			damage. Plant crop in the usual manner.
	(for use in CA only)		When band applications are used on narrow row crops, do not use band widths that will allow treated areas to overlap.
NABAAAA	Nematodes	1.0-4.12 oz/ 1,000 ft of row or 0.9-3.75 lb/A on 36 in. row (15% G) (3 lb/gal EC)	Preplant soil treatment. Band application. Apply specific dosage in front of the planter shoe as a spray or granular application on a 12 to 18 inch band. Incorporate the product into the soil to a dpeth of 2 to 6 inches. Use the higher rates in fields with high populations of nematodes or in fields having a history of serious nematode damage.
		4.0-6.0 lb/A (15% G) (3 lb/gal EC)	Preplant soil treatment. Broadcast application. Distribute the granules or spray uniformly over the entire area to be treated and thoroughly incorporate. Use the higher rates in fields with high populations of nematodes or in fields having a history of serious nematode damage. Plant crop in the usual manner.
	TERRESTRIAL NONFOOD CROP		
	(Agricultural Crops)		
/04001DA	Apple (nonbearing/nursery stock)		
/05002DA	Cherry (nonbearing/nursery stock)		
/05004DA	Peach (nonbearing/nursery stock)		
			Refer to TERRESTRIAL FOOD CROP, (Agricultural Crops), Apple cluster, for use and limitation information.

ETHYL 3-METHYL-4-(METHYLTHIO)PHENYL 1-(METHYLETHYL) PHOSPHORAMIDATE (9CA)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/02000DA	Citrus (nonbearing/nursery stock)		
/28038DA	Fruit Trees (nonbearing/nursery stock)		Apply to trees that will not bear fruit within 12 months after application. Do not apply more than once per planting site per year.
/01014DA			
NABAAAA	Nematodes	[SLN] 9-18 lb/A (15% G) (3 lb/gal EC)	SLN - Use limited to CA. Soil treatment. Apply specific dosage per treated acre over the entire area as a broadcast treatment using ground injection equipment to place the material 2 inches below the soil surface. For band, apply as above, proportionately to the band width (a minimum of 50 percent of the row width). Incorporate thoroughly by sprinkler irrigation.
/01014DA	Grapes (nonbearing/nursery stock)		Apply to vines that will not bear fruit within 12 months after the application.
		Refer to Citrus (nonbearing/nursery stock) cluster for use and limitation information.	
/03000DA	Nut Trees (nonbearing/nursery stock)		N.F. Apply to trees that will not bear fruit within 12 months after application. Do not apply more than once per planting site per year.
NABAAAA	Nematodes	[SLN] 9-18 lb/A (15% G) (3 lb/gal EC)	SLN - Use limited to CA. Soil treatment. Apply specific dosage per treated acre over the entire area as a broadcast treatment using ground injection equipment to place the material 2 inches below the soil surface. For band, apply as above, proportionately to the band width (a minimum of 50 percent of the row width). Incorporate thoroughly by sprinkler irrigation.

EPA Index to Pesticide Chemicals

ETHYL 3-METHYL-4-(METHYLTHIO)PHENYL 1-(METHYLETHYL) PHOSPHORAMIDATE (9CA)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/04003DA	**Pears** (nonbearing/nursery stock)		N.F. Apply to trees that will not bear fruit within 12 months after application. Do not apply more than 20 pounds per planting site per year.
NABAAAA	Nematodes	[SLN] 10-20 lb/A (15% G) (3 lb/gal EC)	SLN - Use limited to OR. Soil treatment. Apply specific dosage per treated acre over the entire area as a broadcast treatment or proportionately to a 4 to 6 foot band over the orchard row. Incorporate thoroughly by sprinkler irrigation.
/26003AA	**Tobacco**		N.F. Not for use on shadegrown tobacco.
NABAAAA	Nematodes	4.0-6.0 lb/A (15% G) 003125-00236 (3 lb/gal EC) 003125-00283	Preplant soil treatment. Broadcast application. Distribute the granules or spray uniformly over the entire area to be treated and incorporate to a depth of 2 to 4 inches by disking or tilling to insure uniform distribution. (Use a minimum of 20 gallons per acre for the emulsifiable concentrate formulation.) Use the higher rates in fields with high populations of nematodes or in fields having a history of serious nematode damage. Plant crop in the usual manner.
NEOBCAA	Root-knot nematode	[SLN] 2.0-3.0 lb/A (2 lb/gal EC)	SLN - Use limited to GA, MD, NC, SC, and VA. At planting soil treatment. Dilute 1 gallon of the product in 10 to 50 gallons of water and apply uniformly to the area to be treated. Use the higher rate in fields with high populations of nematodes or in fields having a history of serious nematode damage. Bed-up over the row and plant crop in the usual manner. Formulated with O,O-diethyl O-(P-(methylsulfinyl)phenyl phosphorothioate.

ETHYL 3-METHYL-4-(METHYLTHIO)PHENYL 1-(METHYLETHYL) PHOSPHORAMIDATE (9CA)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Tobacco (continued)		
			May be tank mixed with metalaxyl and several herbicides. Tank mixing is not approved for MD and VA has approved tank mixing for metalaxyl only.
		[SLN] 2.0-3.0 lb/A (5% G)	SLN - Use limited to GA, MD, SC, and VA. At planting soil application. Apply uniformly to the area to be treated. Use the higher rate in fields with high populations of nematodes or in fields having a history of serious nematode damage. Bed-up over the row and plant crop in the usual manner. Formulated with O,O-diethyl O-(P-(methylsulfinyl)phenyl phosphorothioate.
WEFBBBB /	Tobacco cyst nematode	[SLN] 2.0-3.0 lb/A (2 lb/gal EC)	SLN - Use limited to VA. At planting soil treatment. Dilute 1 gallon of the product in 10 to 50 gallons of water and apply uniformly to the area to be treated. Use the higher rate in fields with high populations of nematodes or in fields having a history of serious nematode damage. Bed-up over the row and plant crop in the usual manner. Formulated with O,O-diethyl O-(P-(methylsulfinyl)phenyl phosphorothioate. May be tank mixed with metalaxyl.

ETHYL 3-METHYL-4-(METHYLTHIO)PHENYL 1-(METHYLETHYL) PHOSPHORAMIDATE (9CA)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	(Ornamental Plants and Forest Trees)		
/31021AA	Anthurium		Do not apply more than twice during any 12 month period.
NABAAAA	Nematodes	1.9-3.4 oz/ 1,000 sq.ft or 5.1-10.5 lb/A (10% G) 003125-00237	Apply uniformly to the area to be treated and irrigate immediately with a minimum of 0.5 inch of water.
/31069AA	Ajuga, 'Metallica' (nursery stock)		Do not apply more than once per year per planting site. Re-entry interval is 48 hours unless impervious boots and gloves are worn. In addition for a 7 day period following completion of an application, impervious gloves and boots must be worn when entering treated fields that are muddy.
/34022AA	Azalea (nursery stock)		
/34031AA	Boxwood (nursery stock)		
/31046AA	Cacti (nursery stock)		
/34042AA	Clematis (nursery stock)		
/34045AA	Cotoneaster (nursery stock)		
/34039AA	English Ivy, 'Baltic' (nursery stock)		
/34053AA	Euonymus (nursery stock)		
/34058AA	Firethorn (nursery stock)		
/35056AA	Flowering Crab (nursery stock)		
/35055AA	Flowering Cherry (nursery stock)		
/34063AA	Gardenia (nursery stock)		
/34069AA	Hibiscus (nursery stock)		
/34070AA	Holly (nursery stock)		
/31126AA	Iris (nursery stock)		
/34078AA	Japanese Andromeda (nursery stock)		
/35073AA	Juniper (nursery stock)		
/31128AA	Plantain-Lily, 'Grandiflora' (nursery stock)		
/34106AA	Pachysandra (nursery stock)		
/33103AA	Periwinkle (nursery stock)		
/35098AA	Pine (nursery stock)		
/34118AA	Rhododendron (nursery stock)		
/34120AA	Rose (nursery stock)		
/33125AA	Sedum (nursery stock)		
/35116AA	Spruce (nursery stock)		
/34137AA	Viburnum (nursery stock)		
/35130AA	Yews (nursery stock)		
/34143AA	Yucca (nursery stock)		
NABAAAA	Nematodes	18.0 lb/A (10% G) 003125-00237	Soil application. Apply uniformly to the area to be treated. Irrigate immediately after treatment using a minimum of 0.5 inch of water. If nursery stock other than those list-

ETHYL 3-METHYL-4-(METHYLTHIO)PHENYL 1-(METHYLETHYL) PHOSPHORAMIDATE (9CA)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	Ajuga, 'Metallica' (nursery stock) (continued)		ed are to be treated, treat a few plants first and observe for phytotoxicity before treating on a large scale.
/33016AA /33017AA /33019AA /33023AA	Bentgrass Bermudagrass Bluegrass Centipedegrass		For use only on golf courses, cemeteries, sod farms, industrial grounds, parkways, and roadways. Do not use on residential lawns or public recreational areas other than golf courses. Do not apply more than twice per year. Do not treat newly seeded areas until the plants have developed secondary roots.
NABAAAA	Nematodes	0.233-0.467 lb/1,000 sq.ft or 10-20 lb/A (10% G) 003125-00237	Soil application. Apply uniformly to the area to be treated and irrigate immediately using a minimum of 0.5 inch of water.
/31126AA /31131AA /31142AA	Iris (bulbs) Lily (bulbs) Narcissus (bulbs)		Bulbs may vary as to their phytotoxic sensitivity to fenamiphos. Test a small number of plants if this sensitivity is not locally known. Do not apply to green foliage.
NABAAAA	Nematodes	6.0-12.0 lb/A or 0.475-0.95 lb/100 ft of row (10% G) 003125-00237	Soil application. Apply at planting time so that the material is incorporated into the covering soil or in a 10 to 12 inch band over the row after planting. For year old plantins, apply over the row as a fall application (October through December). Incorporate with irrigation or rain water as soon as possible after application.

ETHYL 3-METHYL-4-(METHYLTHIO)PHENYL 1-(METHYLETHYL) PHOSPHORAMIDATE (9CA)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
/39010AA	Leatherleaf Fern		
NABAAAA	Nematodes	10.0 lb/A (10% G) 003125-00237	Soil application. Apply uniformly to the area to be treated and irrigate immediately with a minimum of 0.5 inch water.
/31005AA	Ornamental Flower Bulbs		Use limited to CA. One application and 12 pounds per year maximum.
NABAAAA	Nematodes	[SLN] 12.0 lb/A (15% G) (3 lb/gal EC)	Soil application. Apply at planting time, so that the material is incorporated into the covering soil or in a 10 to 12 inch band over the row after planting.
/34005DA /35000DA	Ornamental Woody Vines (nursery) Ornamental Trees (nursery)		Do not apply more than once per planting site per year.
NABAAAA	Nematodes	[SLN] 9-18 lb/A (15% G) (3 lb/gal EC)	SLN - Use limited to CA. Soil treatment. Apply specific dosage per treated acre over the entire area as a broadcast treatment using ground injection equipment to place the material 2 inches below the soil surface. For band, apply as above, proportionately to the band width (a minimum of 50 percent of the row width). Incorporate thoroughly by sprinkler irrigation.
/34468AA	Protea		Do not apply more than twice per planting site per year.
NABAAAA	Nematodes	[SLN] 0.1-0.225 lb/ 1,000 sq.ft or 4.5-9.75 lb/A (15% G)	SLN - Use limited to HI. Postplant soil treatment. Apply specific dosage per unit area and incorporate mechanically into upper 2 to 3 inches of soil, then irrigate immediately using a minimum of 0.5 inch of water.

ETHYL 3-METHYL-4-(METHYLTHIO)PHENYL 1-(METHYLETHYL) PHOSPHORAMIDATE (9CA)

	Site and Pest	Dosages and Formulation(s)	Tolerance, Use, Limitations
	AERIAL AND TANK MIX APPLICATIONS		
9900300 AAAAAAA	Tank Mix --		Refer to TERRESTRIAL NONFOOD CROP (Agricultural Crops) Apple (nonbearing/nursery stock) [SLN], Cherry (nonbearing/nursery stock) [SLN], Peach (nonbearing/nursery stock) [SLN], Tobacco [SLN]

ETHYL 3-METHYL-4-(METHYLTHIO)PHENYL 1-(METHYLETHYL) PHOSPHORAMIDATE (9CA)

Listing of Registered Pesticide Products by Formulation

&085.0001 85% technical chemical
ethyl 3-methyl-4-(methylthio)phenyl 1-(methylethyl) phosphoramidate (9CA) (100601)
003125-00269

&072.3002 72.3% formulation intermediate
ethyl 3-methyl-4-(methylthio)phenyl 1-(methylethyl) phosphoramidate (9CA) (100601)
003125-00333

&005.0004 5% granular
ethyl 3-methyl-4-(methylthio)phenyl 1-(methylethyl) phosphoramidate (9CA) (100601) plus O,O-diethyl O-(P-(methylsulfinyl)phenyl phosphorothioate (032701)
GA790003 SC790008 VA790003

&010.0004 10% granular
ethyl 3-methyl-4-(methylthio)phenyl 1-(methylethyl) phosphoramidate (9CA) (100601)
003125-00237

&015.0004 15% granular
ethyl 3-methyl-4-(methylthio)phenyl 1-(methylethyl) phosphoramidate (9CA) (100601)
003125-00236

AL820011 AR800005 CA790185 CA820012
CA830062 DE780015 FL780026 GA780001
GA780014 GA800015 HI770002 IN790002
KY790002 LA800003 LA810015 MD790006
ME780001 MI770018 MI770019 MO780008
MO780009 MS800006 NC780002 NM790020
NY780002 NY810008 OK780008 OR790072
OR800064 OR840034 PA770012 SC780001
SC790005 SC800018 TN780004 TN800007
TX790036 UT790008 WA760033 WA790032
WA840055 WV780001

&202.0012 2 lb/gal (21%) emulsifiable concentrate
ethyl 3-methyl-4-(methylthio)phenyl 1-(methylethyl) phosphoramidate (9CA) (100601) plus O,O-diethyl O-(P-(methylsulfinyl)phenyl phosphorothioate (032701)
GA790002 MD820003 NC780036 SC790007
VA790003

&203.0012 3 lb/gal (35%) emulsifiable concentrate
ethyl 3-methyl-4-(methylthio)phenyl 1-(methylethyl) phosphoramidate (9CA) (100601)
003125-00283

ETHYL 3-METHYL-4-(METHYLTHIO)PHENYL 1-(METHYLETHYL) PHOSPHORAMIDATE (9CA)

Listing of Registered Pesticide Products by Formulation (continued)

3 lb/gal (35%) emulsifiable concentrate (continued)

AL820012 AR800004 CA790185 CA820011
CA820101 CA830061 DE780014 FL780025
GA780011 GA780023 GA800016 GA840008
IL820003 IN790003 KY790001 LA800004
LA810014 MD790007 MD820005 ME780002
MS800007 NC780019 NM790021 NY780001
NY810007 OH810019 OK780007 OR790071
OR800063 OR840035 PA770013 SC780009
SC790004 SC800017 TN800008 TX790035
UT780035 VA780003 VA780004 VA780010
WA760034 WA790033 WA840056 WV780002

999999 **State Label Registration**

HI Reg. No.
037843-08571

EPA Index to Pesticide Chemicals

ETHYL 3-METHYL-4-(METHYLTHIO)PHENYL 1-(METHYLETHYL) PHOSPHORAMIDATE (9CA)

Appendix A-1

Listing of Active Ingredient(s) Found in Combination With the Report Chemical

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
032701	—	O,O-diethyl O-(P-(methylsulfinyl)phenyl phosphorothioate

— Use EPA Acceptable Common/Chemical Name

ETHYL 3-METHYL-4-(METHYLTHIO)PHENYL 1-(METHYLETHYL) PHOSPHORAMIDATE (9CA)

Appendix A-2

Listing of Active Ingredient(s) Which May Be Included in Tank Mixes

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
metalaxyl		

— Use EPA Acceptable Common/Chemical Name

EPA Index to Pesticide Chemicals

ETHYL 3-METHYL-4-(METHYLTHIO)PHENYL 1-(METHYLETHYL) PHOSPHORAMIDATE (9CA)

Auxiliary Documentation

There is a section 3 10% granular registration (#003125-00237, stamp dated Dec. 19, 1983), which is for non-bearing fruit (deciduous fruit trees, including apples, cherries and peaches). It restricts the use of any fruit forming on trees until one year after treatment. Likewise there are SLN (special local need, 24C registration) registrations, 30 in all, of a similar nature. These are as follows:

15% granular:	DE78001500	IN79000200	LA81001400	MD79000600
	ME78000100	MI77001900	NY78000200	NY81000800
	OR78007200	PA77001200	UT79000800	VA78000300
	WA78003200	WV78000100		
3 lb/gal EC:	DE78001400	IL82000300	IN79000300	LA81001400
	MD78000700	ME78000200	MI77001800	NY78000100
	NY81000700	OH81001900	OR79000700	PA77001300
	UT79000700	VA78001000	WA78003300	WV78000200

There is, however, a section 3 (10% granular) registration label (stamp dated July 22, 1983) which is for fruit crop (including apples, cherries and peaches) which has a PHI (pre-harvest interval) of 72 day for bearing apples and 45 days for bearing cherries and peaches. There are also other section 3 registrations for fenamiphos (a 15% granular bearing stamp dated May 6, 1985 and a 3 pound per gallon EC bearing stamp date July 25, 1985) which are for bearing apples, cherries and peaches having PHI's of 72 and 45 days respectively. It is my judgement (Mr. Henry Jacoby, PM 21 team leader also agrees) that the accepted registrations on bearing fruit trees (apples, cherries and peaches) with PHI's of 72 and 45 days, lift or countermand the one year PHI restriction on the non-bearing deciduous fruit trees. The index entry for fenamiphos has been written to reflect this decision.

Note: Since there are now section 3 registrations to cover all the SLN registrations listed above, it seems that it would be a prudent action to get these off our books.

Signed:

J. Dean Hansen
Plant Pathologist

ETHYL 3-METHYL-4-(METHYLTHIO)PHENYL 1-(METHYLETHYL) PHOSPHORAMIDATE (9CA)

Appendix A-2

Listing of Active Ingredient(s) Which May Be Included in Tank Mixes

Chemical Code	Common Name (source)	EPA Acceptable Common/Chemical Name
113501	metalaxyl	N-(2,6-dimethylphenyl)-N-(methoxyacetyl)-alanine, methyl ester

— Use EPA Acceptable Common/Chemical Name

APPENDIX IV

BIBLIOGRAPHY

GUIDE TO USE OF THIS BIBLIOGRAPHY

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

(1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

(2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.

(3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

(4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

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00052495	Wakefield, M.; Orme, J.P.R.; Mullin, L.W.; et al. (1973) Determination of Residues of Nemacur and Its Metabolites in Bananas: FBA116/73220; Report No. 36283. Method dated Mar 21, 1973. (Unpublished study received May 23, 1973 under 3F1399; prepared by Huntingdon Research Centre, submitted by Chemagro Corp., Kansas City, Mo.; CDL:093749-B)
00052501	Chemagro Corporation (1974) Chemagro Corporation Residue Experiment No. SE-3908-68H: Report No. 27032. (Unpublished study received on unknown date under 3F1399; CDL:093748-G)
00052504	Khasawinah, A.M. (1972) The Uptake and Metabolism of Nemacur Soil Residues by Soybean Plants: Report No. 35012. (Unpublished study received May 23, 1973 under 3F1399; submitted by Chemagro Corp., Kansas City, Mo.; CDL:093748-J)
00052508	Analytical BioChemistry Laboratories, Incorporated (1974) Chemagro Division of Baychem Corporation Residue Experiment: 161-3946-72H: Report No. 36063. (Unpublished study received on unknown date under 3F1399; submitted by Chemagro Corp., Kansas City, Mo.; CDL:093748-Q)
00052509	Khasawinah, A.M. (1973) Metabolism of *(R)†Nemacur in Tomatoes: Report No. 38501. (Unpublished study received on unknown date under 3F1399; submitted by Chemagro Corp., Kansas City, Mo.; CDL:093748-R)
00052510	Khasawinah, A.M. (1973) The Metabolism of Nemacur in Cabbage: Report No. 39120. (Unpublished study received on unknown date under 3F1399; submitted by Chemagro Corp., Kansas City, Mo.; CDL:093748-S)
00052511	Olson, T.J. (1974) The Effect of Alkali Refining on Nemacur Residues in Cottonseed Oil: Report No. 40113. (Unpublished study received on unknown date under 3F1399; submitted by Chemagro Corp., Kansas City, Mo.; CDL:093748-T)
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00052527	Gronberg, R.R. (1969) The Metabolic Fate of...(Bay 68138),...(Bay 68138 Sulfoxide), and...(Bay 68138 Sulfone) by White Rats: Report No. 26759. (Unpublished study received May 23, 1973 under 3F1399; submitted by Chemagro Corp., Kansas City, Mo.; CDL:093743-U)
00055868	Mobay Chemical Corporation (1977) Addition to Synopsis of Nemacur: Residue Chemistry on Various Crops. (Unpublished study received Nov 19, 1979 under 3125-283; CDL:241444-A)
00056049	Mobay Chemical Corporation (1976) Effect of Nemacur Residue on Oranges and Lemons: Report No. 47140. (Compilation; unpublished study including report nos. 47141, 47142, 47143..., received Sep 10, 1976 under 3125-236; CDL:095284-D)
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00075270	Burrows, I.E.; Way, D. (1971) Determination of Bay 68138 (Nemacur) and Its Metabolites in Bananas: Report No. 3990/71/148; Report No. 30203. (Unpublished study received 1974 under 4E1458; prepared by Huntingdon Research Centre, England, submitted by Mobay Chemical Corp., Kansas City, Mo.; CDL:093878-J)
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00082807	DuBois, K.P.; Flynn, M.; Kinoshita, F. (1967) The Acute Toxicity and Anticholinesterase Action of Bayer 68138: Submitter 20810. (Unpublished study received on unknown date under 0F0982; prepared by Univ. of Chicago, Toxicity Laboratory, submitted by Chemagro Corp., Kansas City, Mo.; CDL:098068-C)
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00103094	Mobay Chemical Corp. (1981) Nemacur Residue Chemistry on Garlic: AS 82-1314. (Compilation; unpublished study received May 20, 1982 under 3125-263; CDL:070880-A)
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00106037	Interregional Research Project No. 4 (1979) The Results of Tests on the Amount of Fenamiphos Residues Remaining in or on Okra, Including a Description of the Analytical Method Used. (Compilation; unpublished study received Jul 12, 1982 under 2E2724; CDL:070972-A)
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00112903	Mobay Chemical Corp. (1982) Nemacur Residue Chemistry on Apples, Cherries and Peaches: Addition No. 2 to Brochure Entitled: Nemacur Residue Chemistry on Apples, Cherries and Peaches: AS 82-1999. (Compilation; unpublished study received Sep 1, 1982 under 3125-236; CDL:071065-A)

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00161361	Hayes, R. (1986) Combined Chronic Toxicity/Oncogenicity Study of Technical Fenamiphos (Nemacur) with Rats: Study No. 83-271-01: Mobay Report No. 91750. Unpublished study prepared by Mobay Chemical Corp. 1095 p.
00165546	Mobay Chemical Corp. (1981) Nemacur: Residue Chemistry on Cocoa Beans. Unpublished compilation. 69 p.
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APPENDIX V

FORMS

OMB Approval No. 2000-0468 (Expires 12-31-83)

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO.
PRODUCT NAME	
APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

OMB Approval No. 2000-0468 (Expires: 12-31-83)

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items or data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)

PRODUCT SPECIFIC DATA REPORT

EPA Reg. No.____________________ Date __________________________

Guidance Document for ____

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
§158.120 PRODUCT CHEMISTRY					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				

Registration Guideline No.	Name of Test	Test not required for my product listed above (check below)	I am complying with data requirements by		(For EPA Use Only) Accession Numbers Assigned
			Citing MRID Number or EPA Accession Number	Submitting Data (Attached)	
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion characteristics				
63-21	Dielectric breakdown voltage				
§158.135 TOXICOLOGY					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation, toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

164 OMB Approval No. 2070-0057
Expiration Date 11/30/89

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number: ______________

Registrant's Name and Address: ______________________

____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated __________ concerning a requirement for submission of "generic" data on the active ingredient ____________ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidential Statement of Formula(CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated _________ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form No. 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are ____________________ and their registration number(s) is/are ______________ .

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative: ____________________________
(Signature)

Dated: ________________ ____________________________
(Typed)

EPA Form 8570-27